SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY, et al.,

Defendants.

_____/

Proceedings held on Thursday, July 12, 2018, Volume 8, Morning Session, before the Honorable Suzanne R. Bolanos, at 9:23 a.m.

REPORTED BY:

LESLIE ROCKWOOD ROSAS, RPR, CSR 3462

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Department 504

Judge Suzanne Ramos Bolanos

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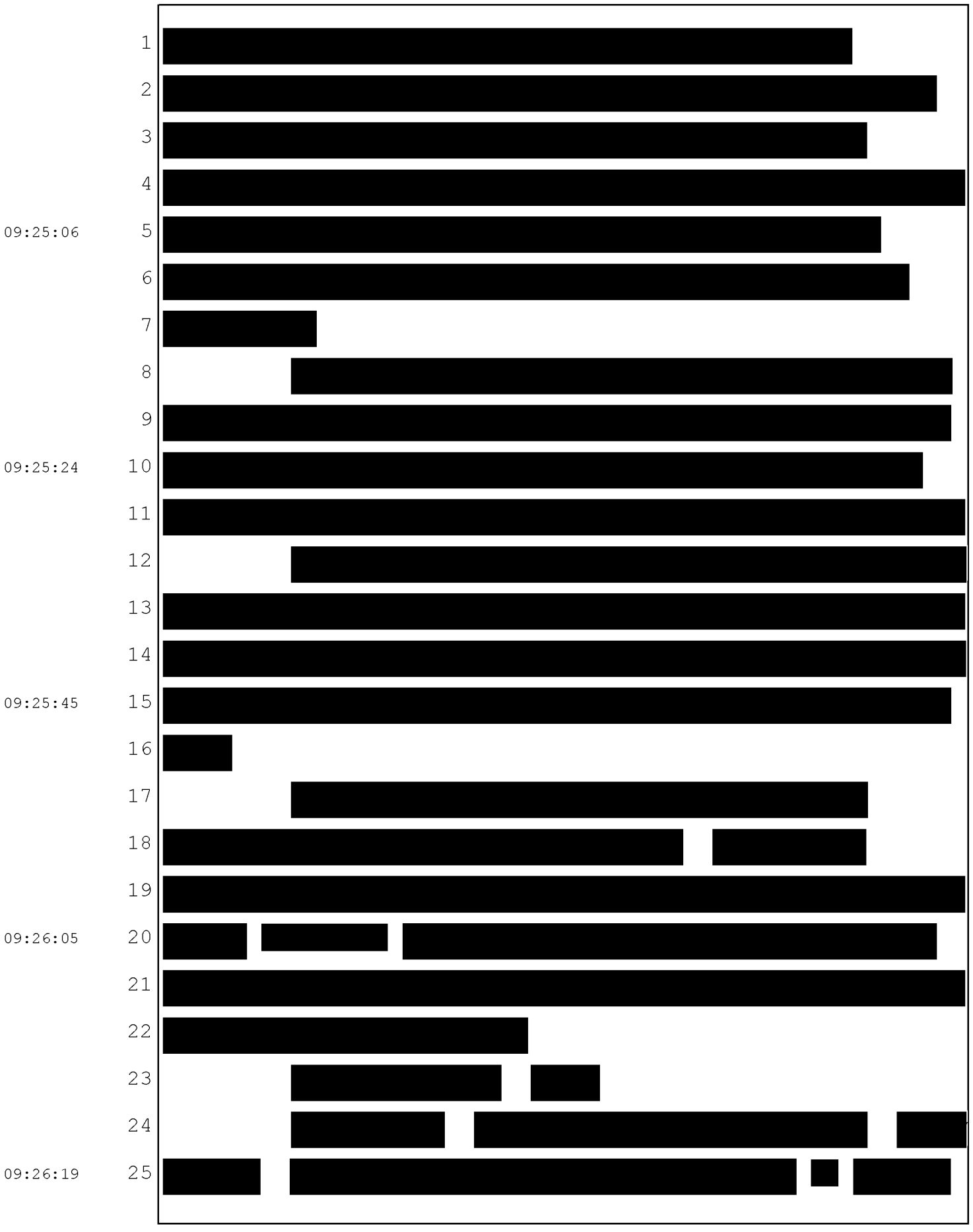
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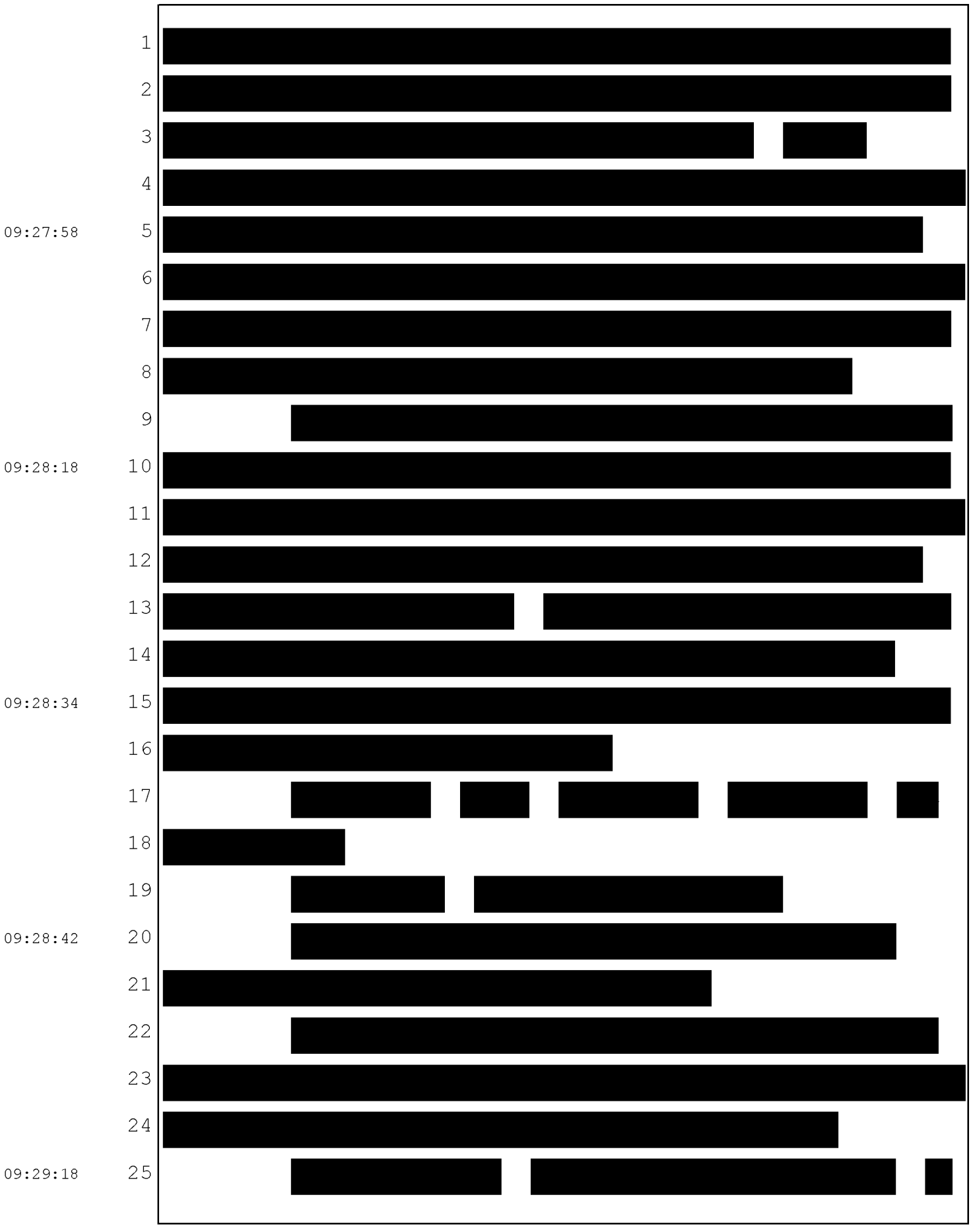
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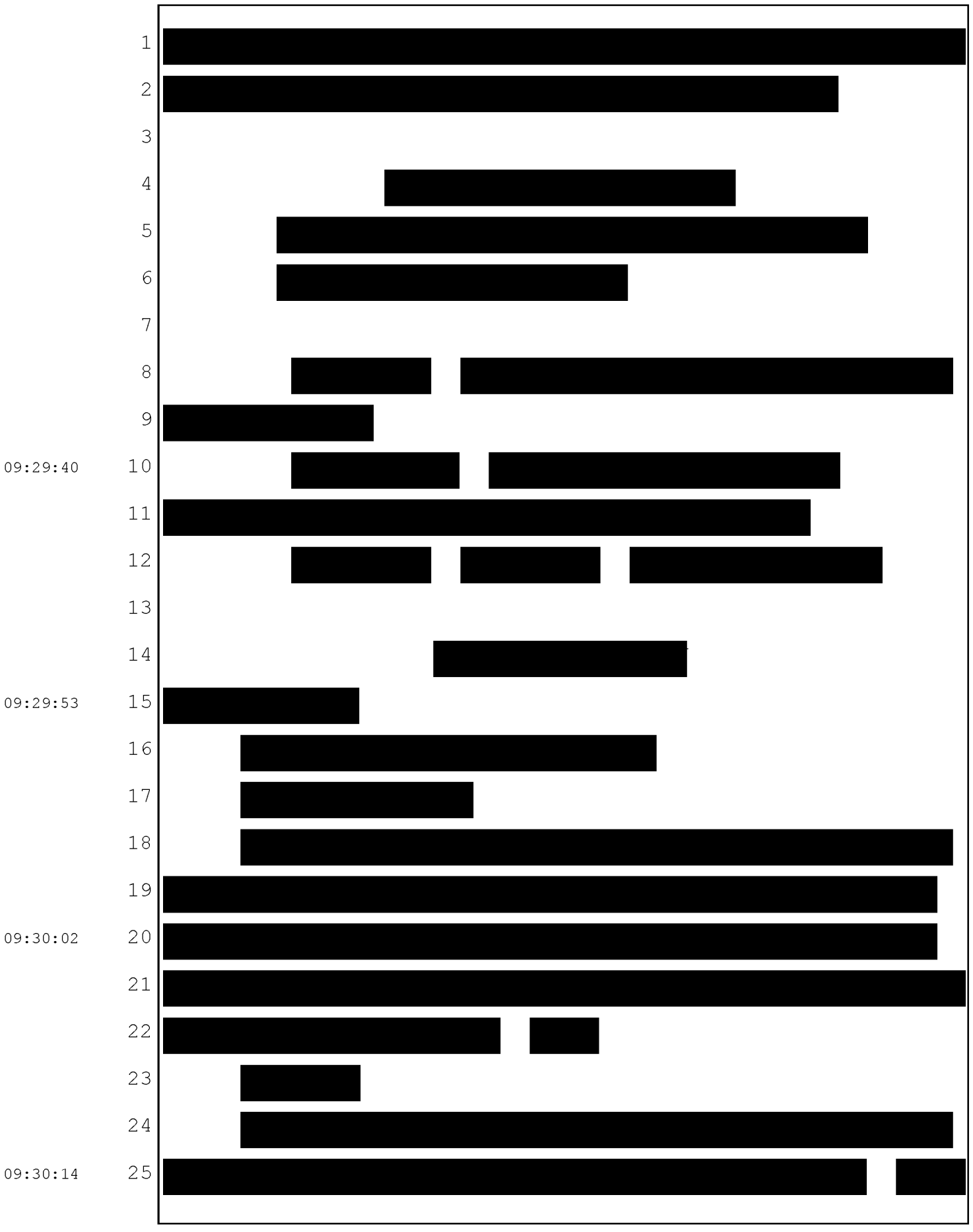
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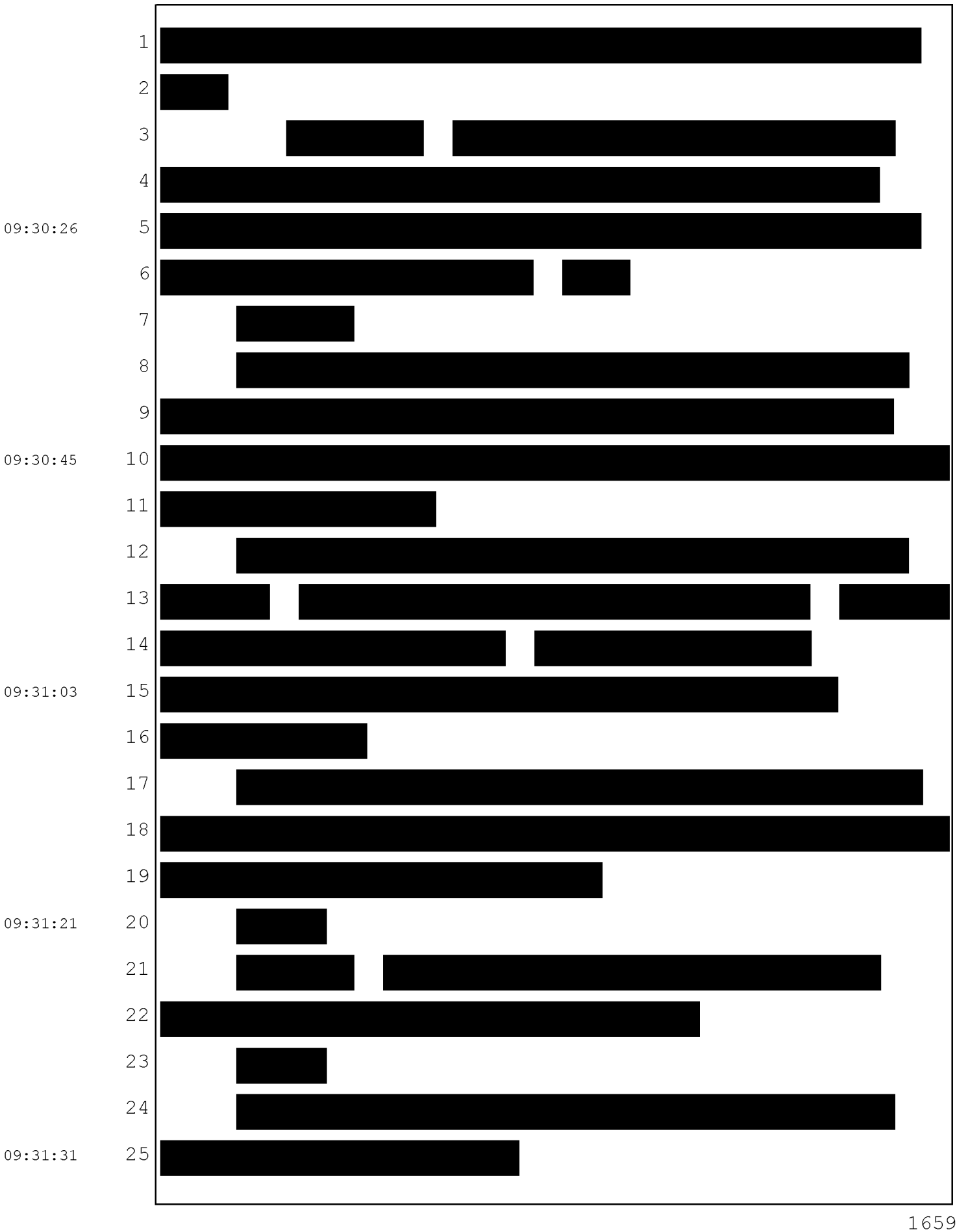
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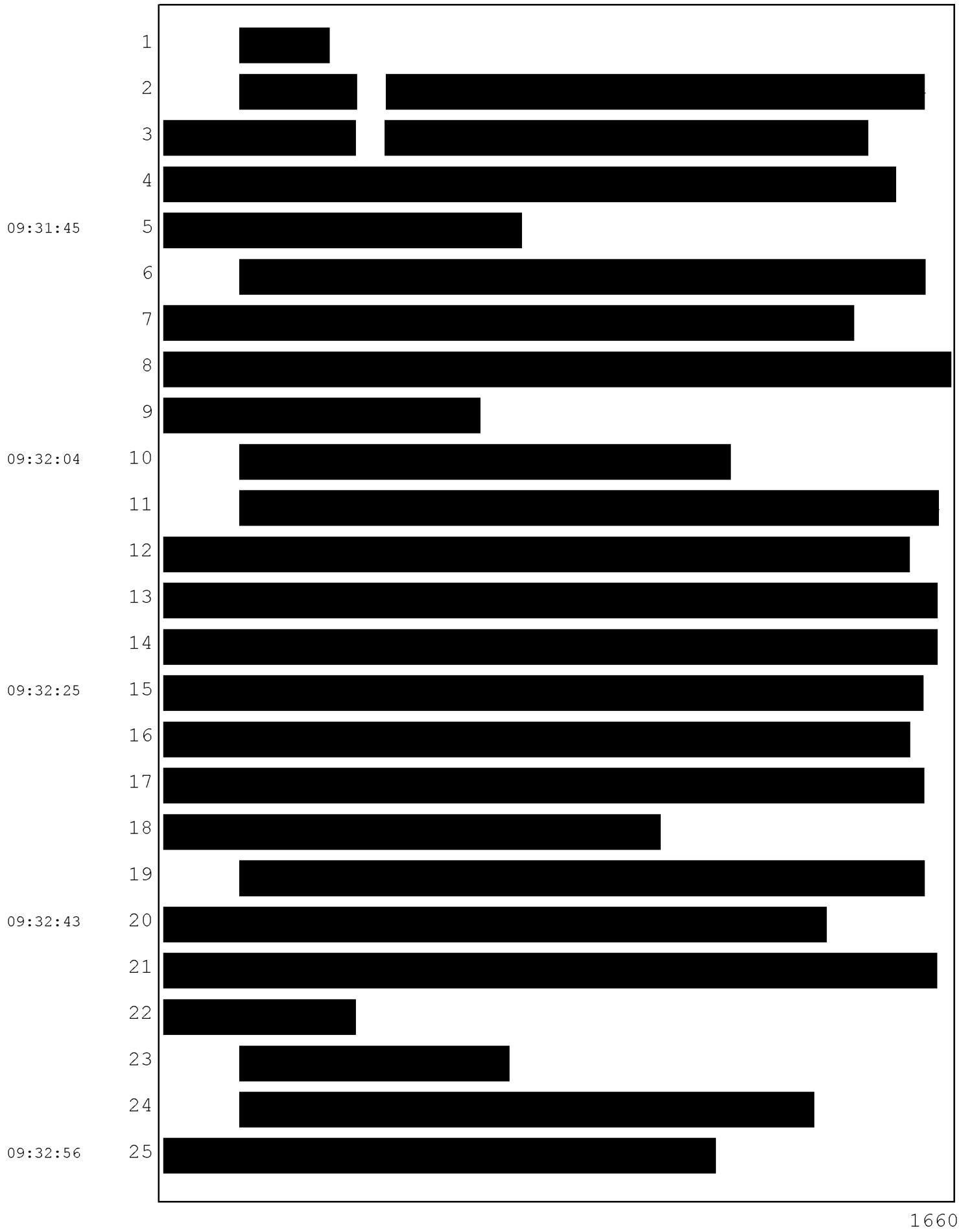
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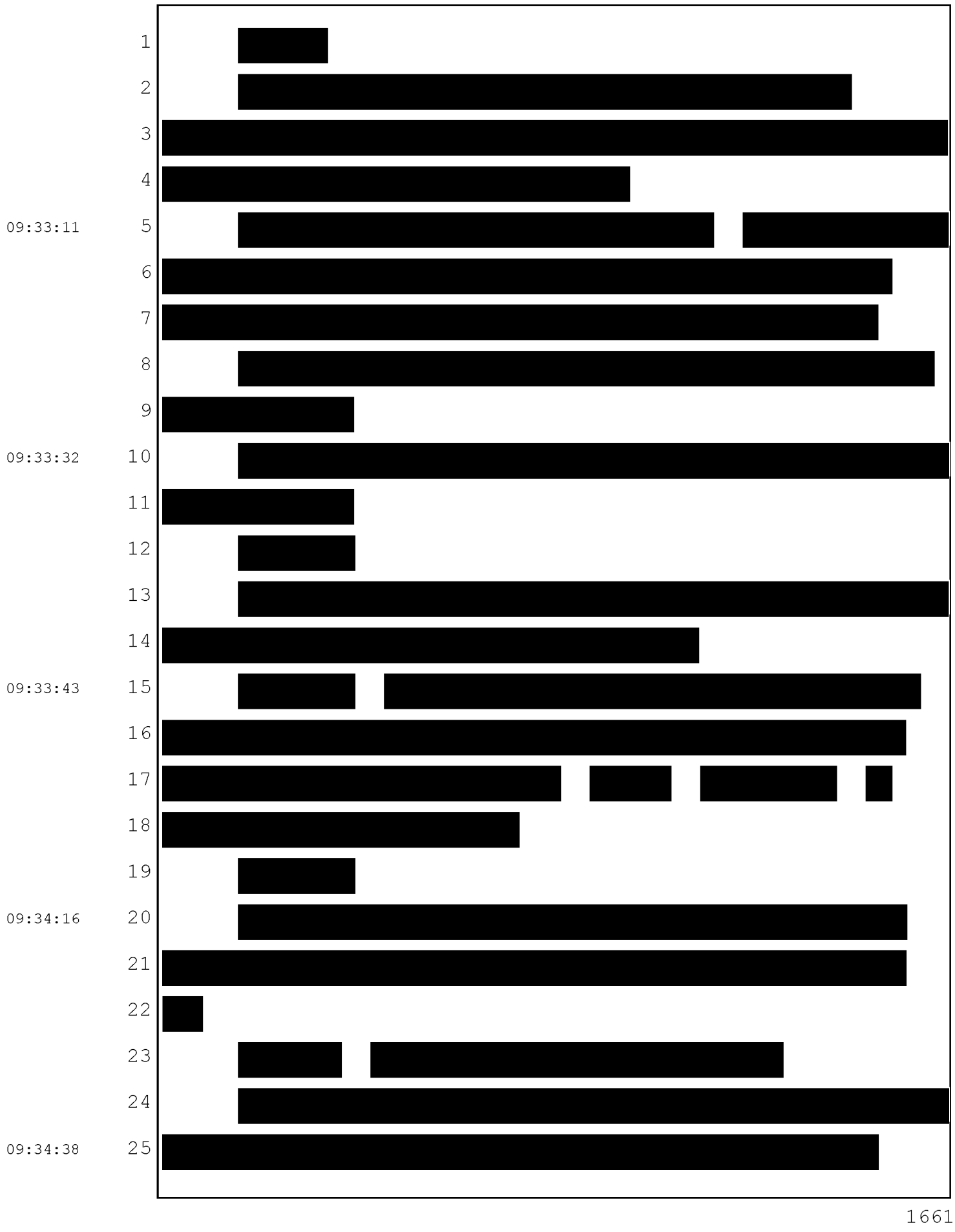
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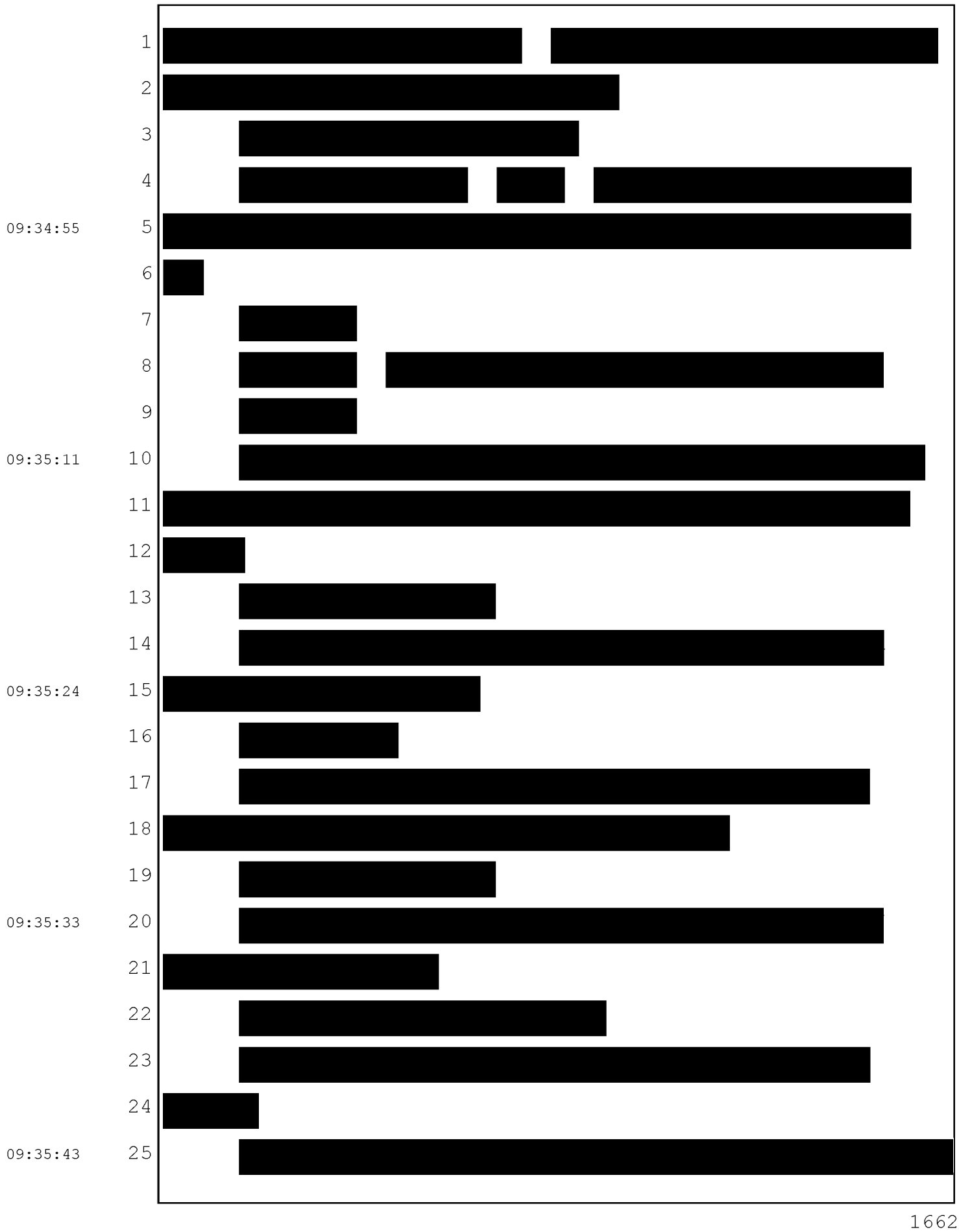
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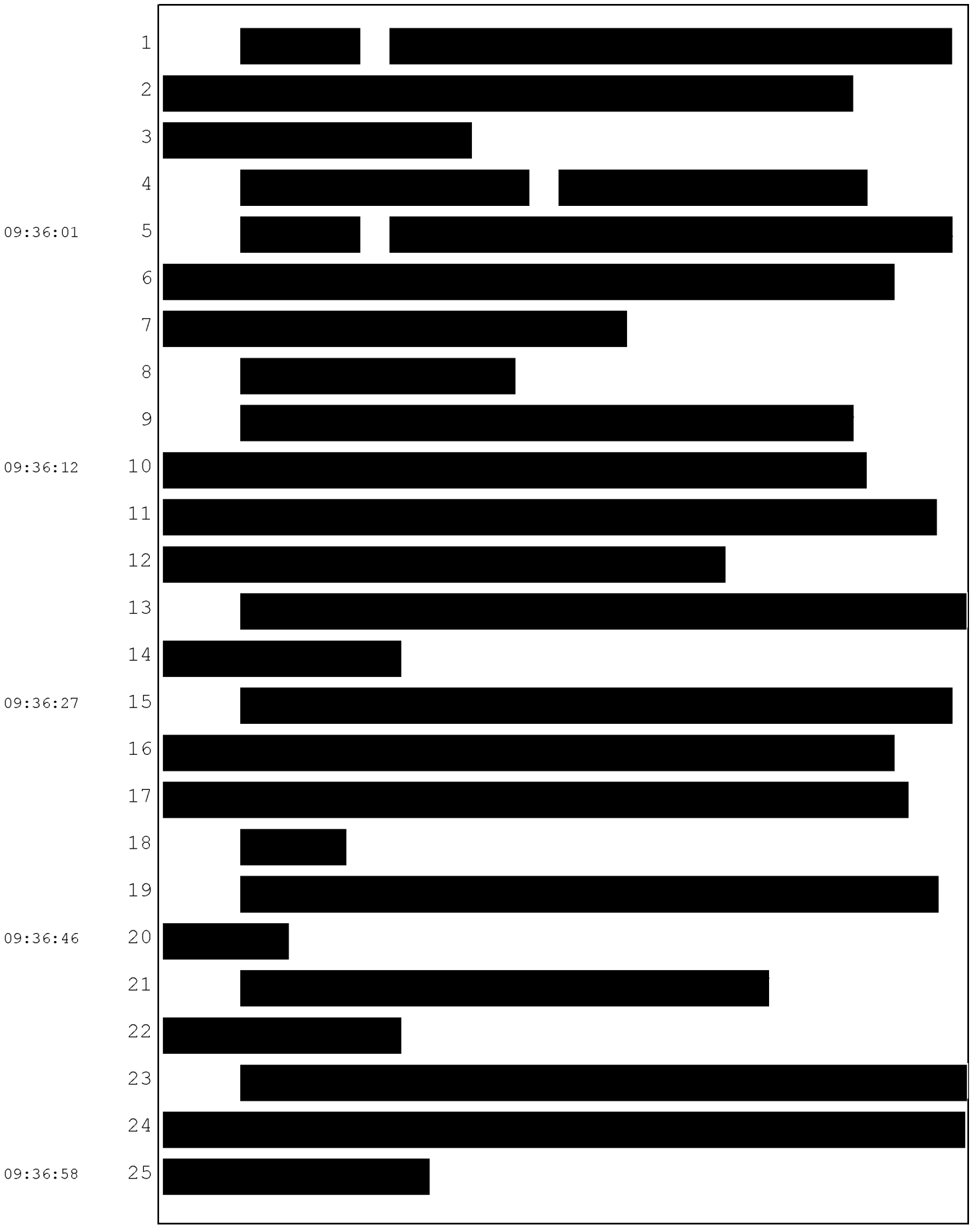
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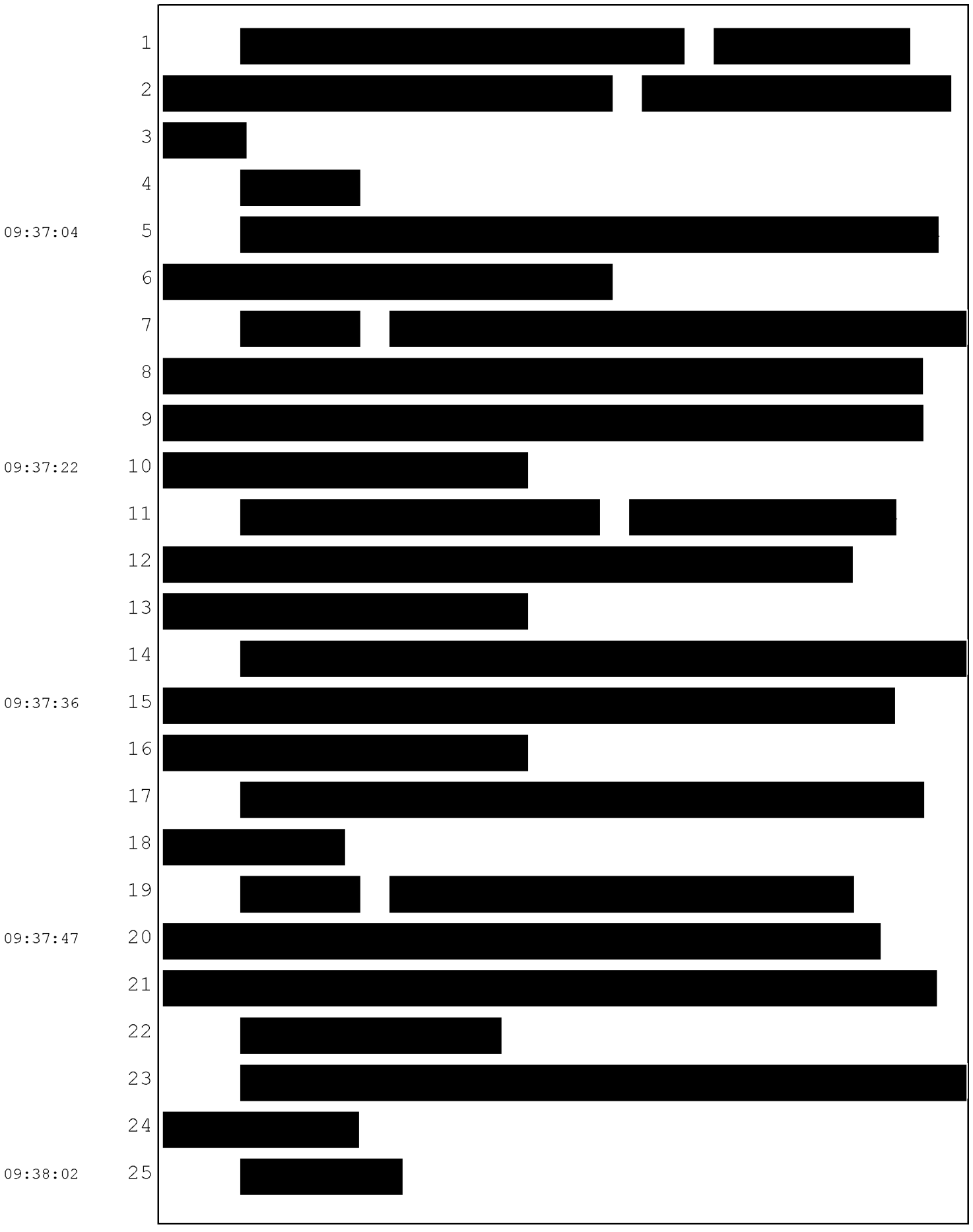
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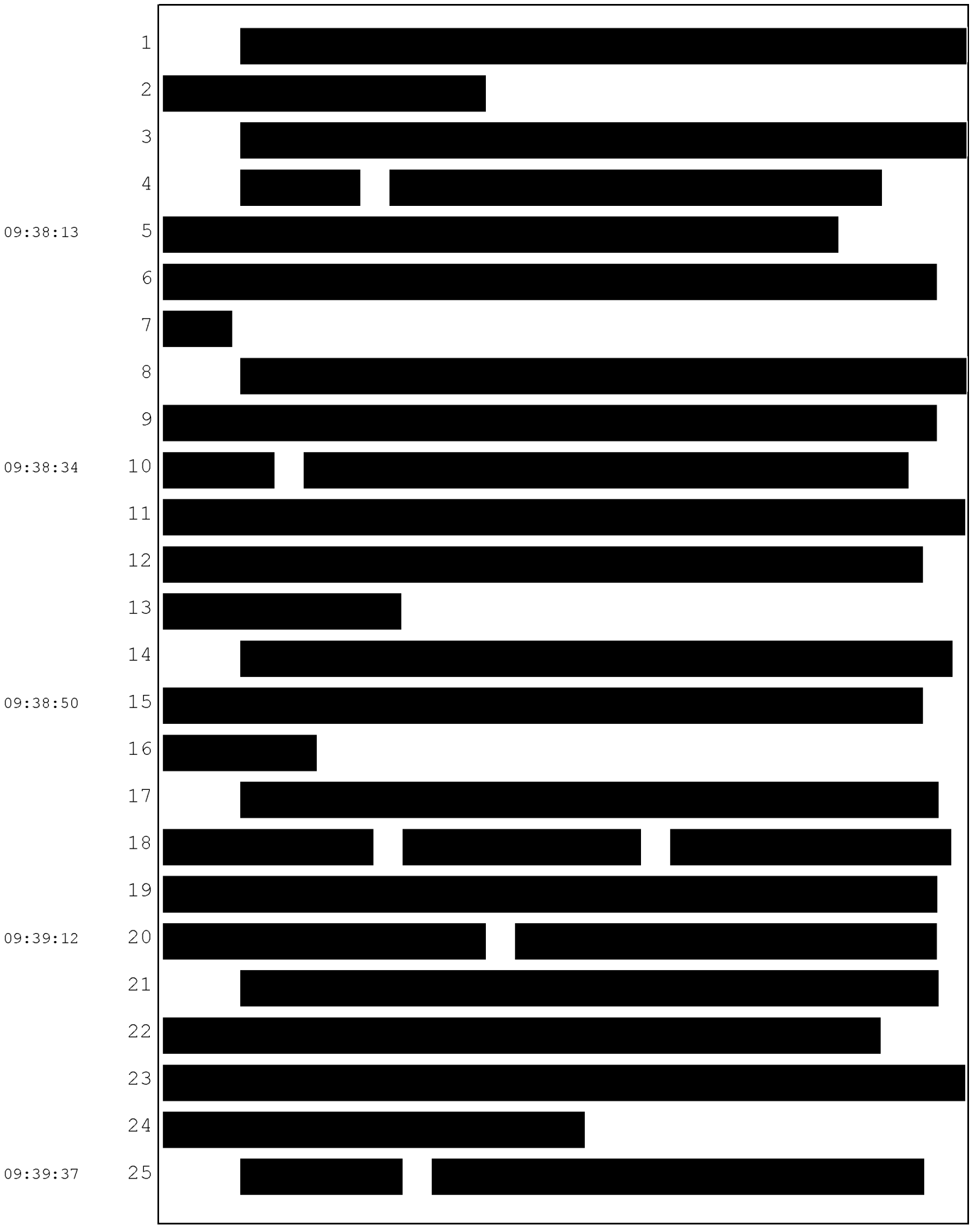
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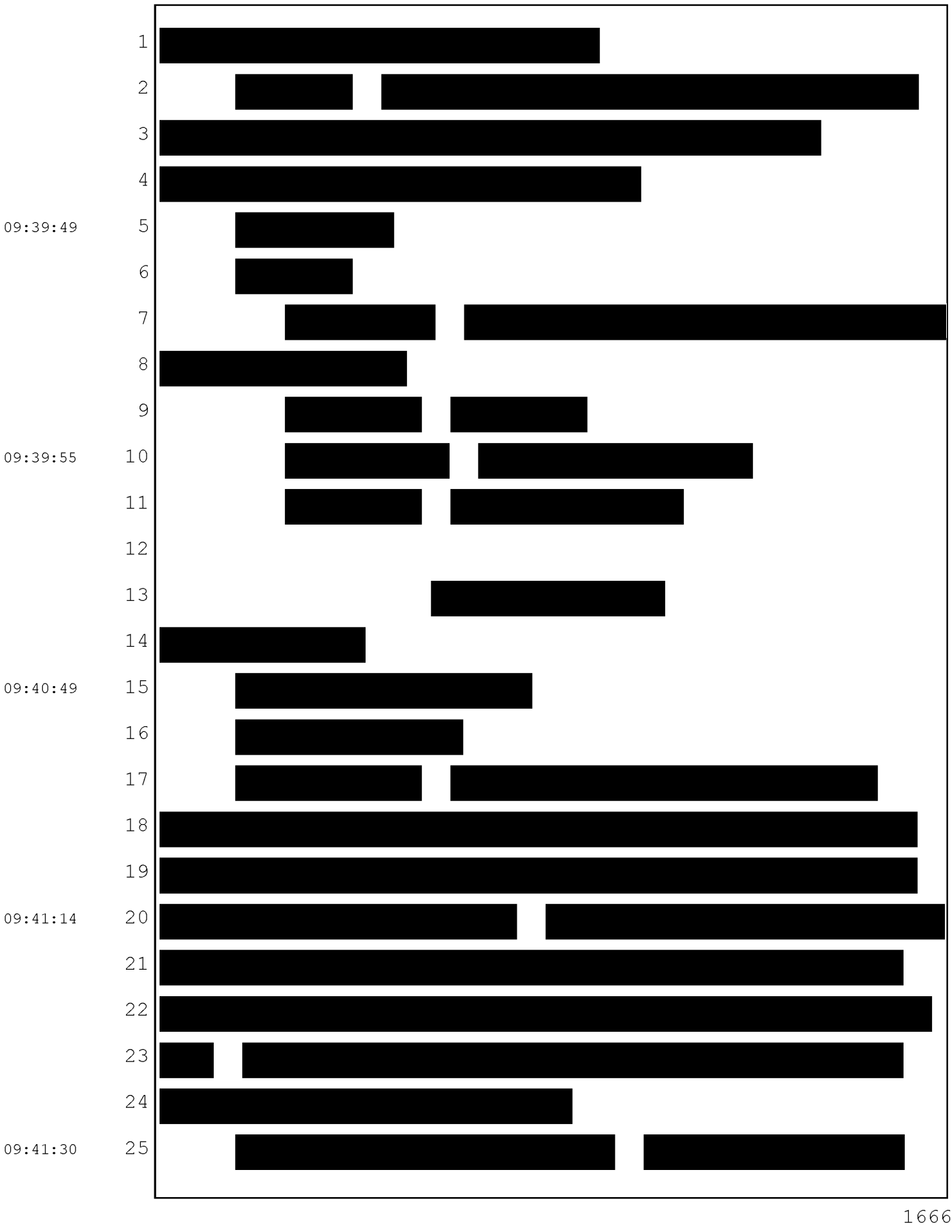
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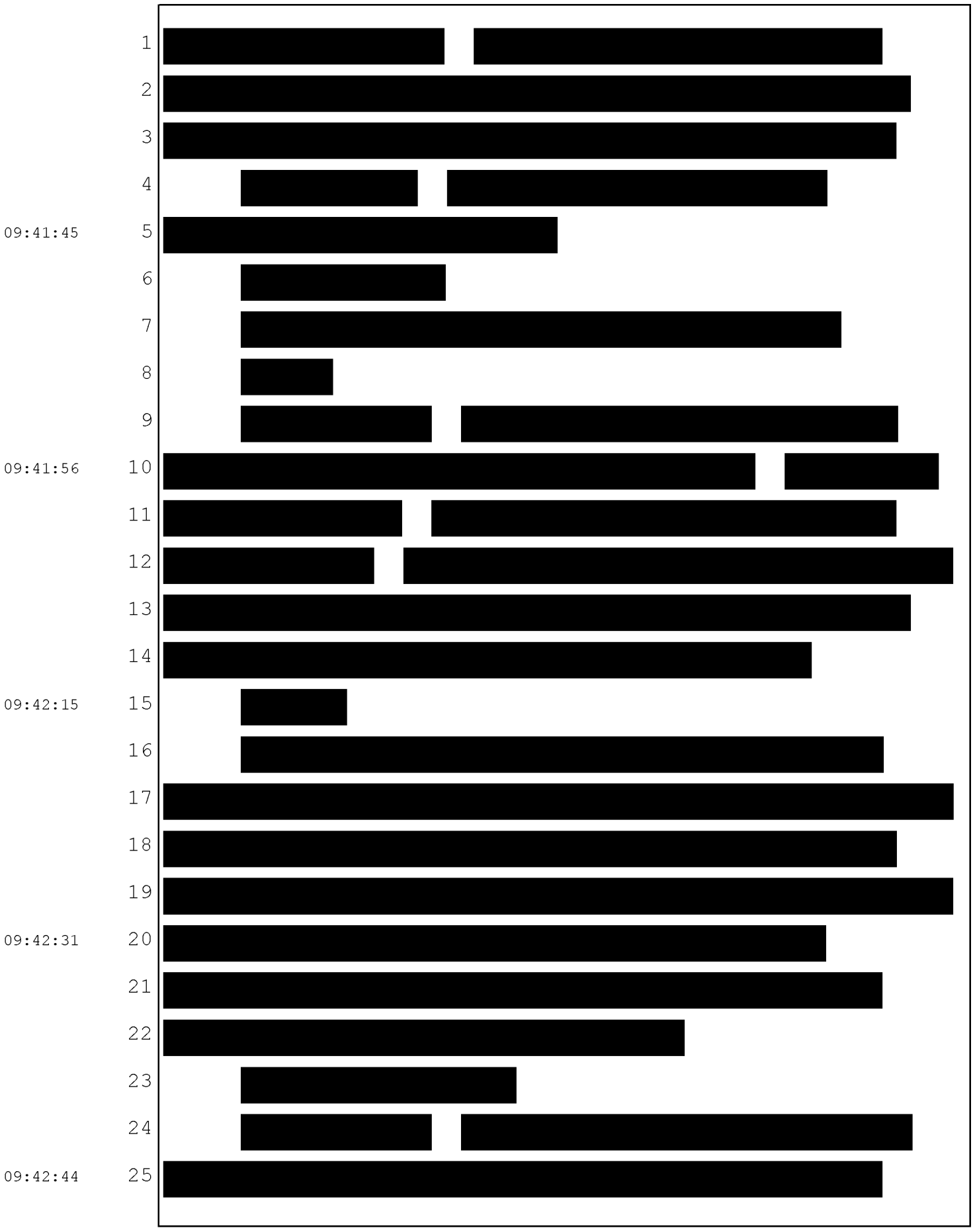
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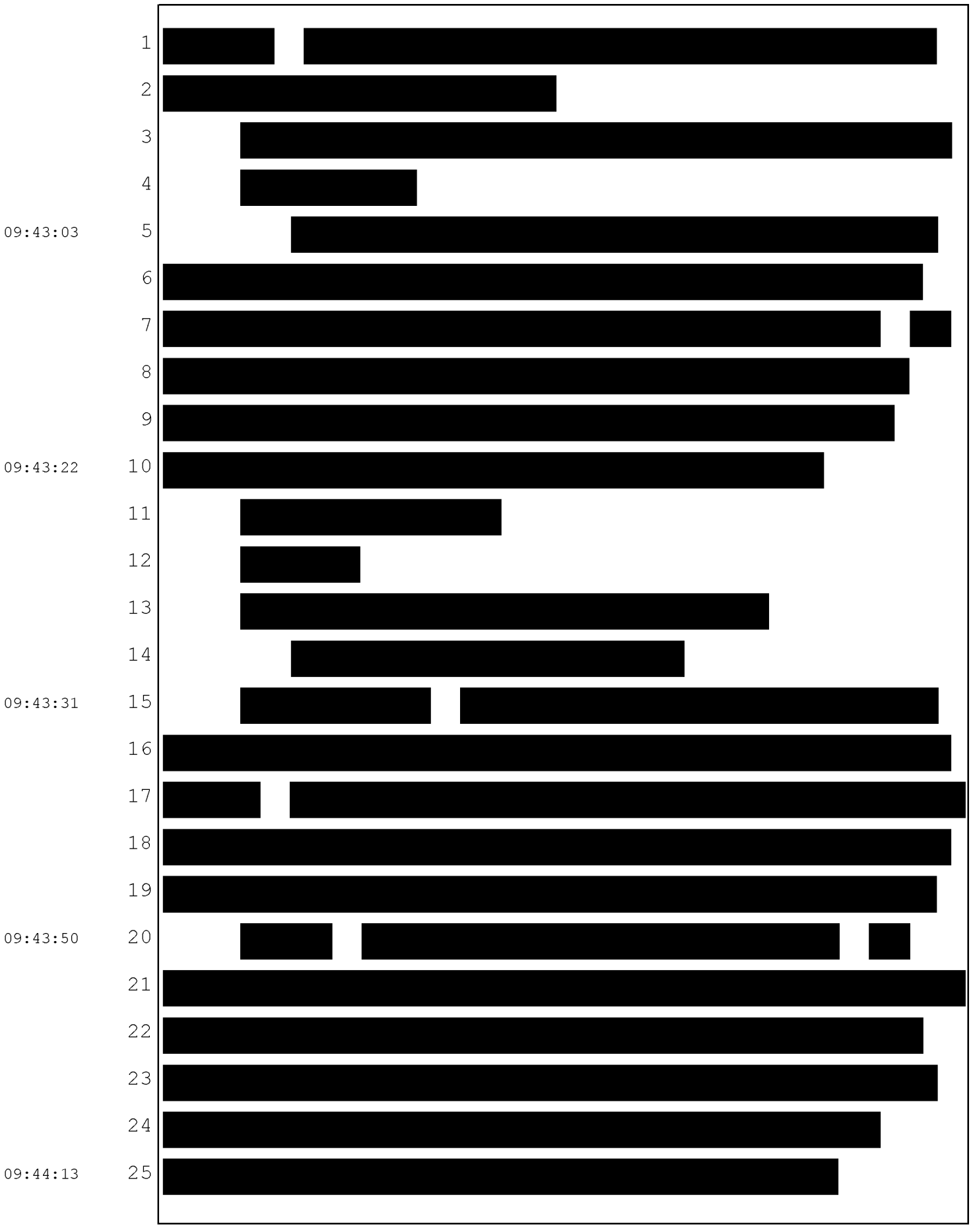
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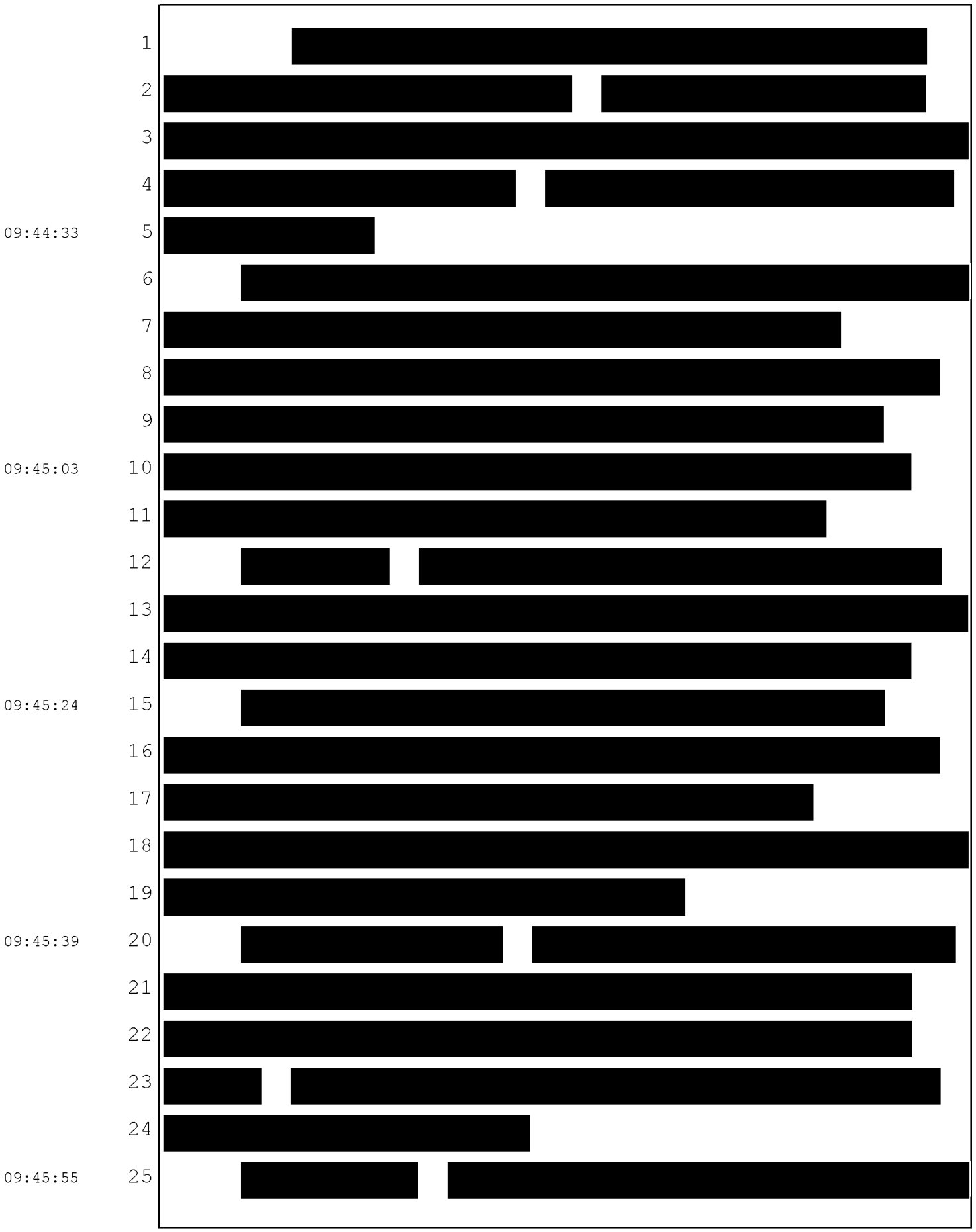
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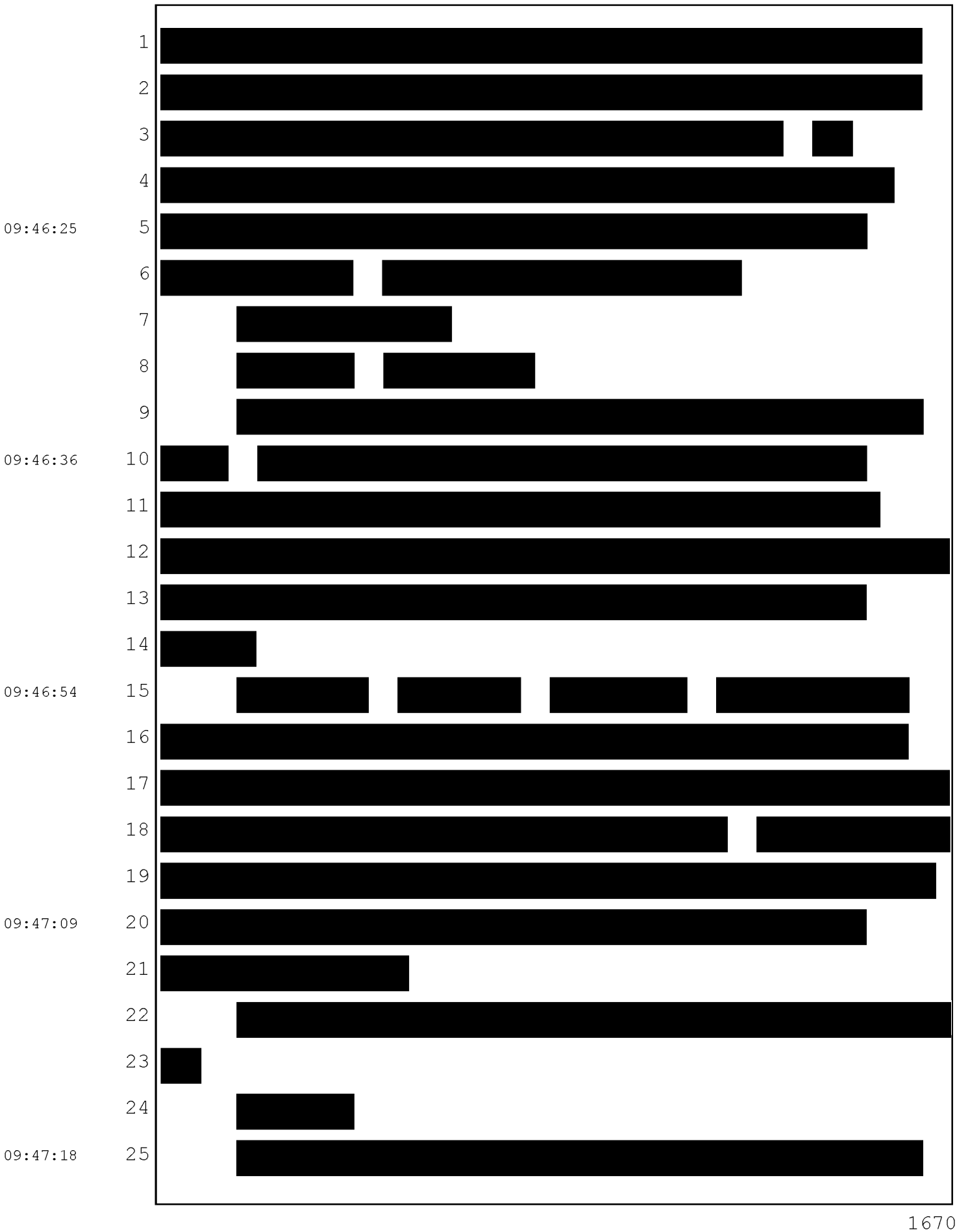
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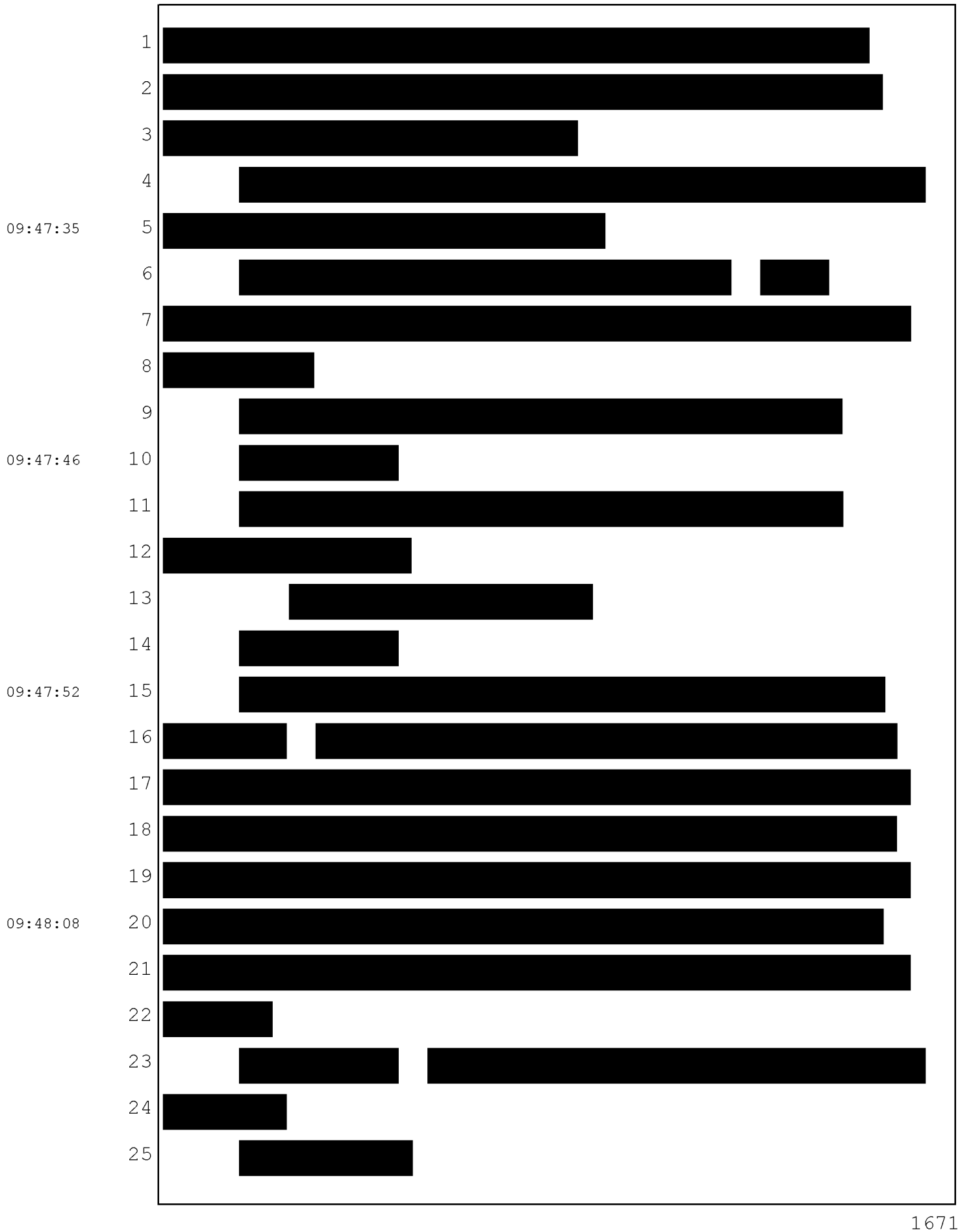
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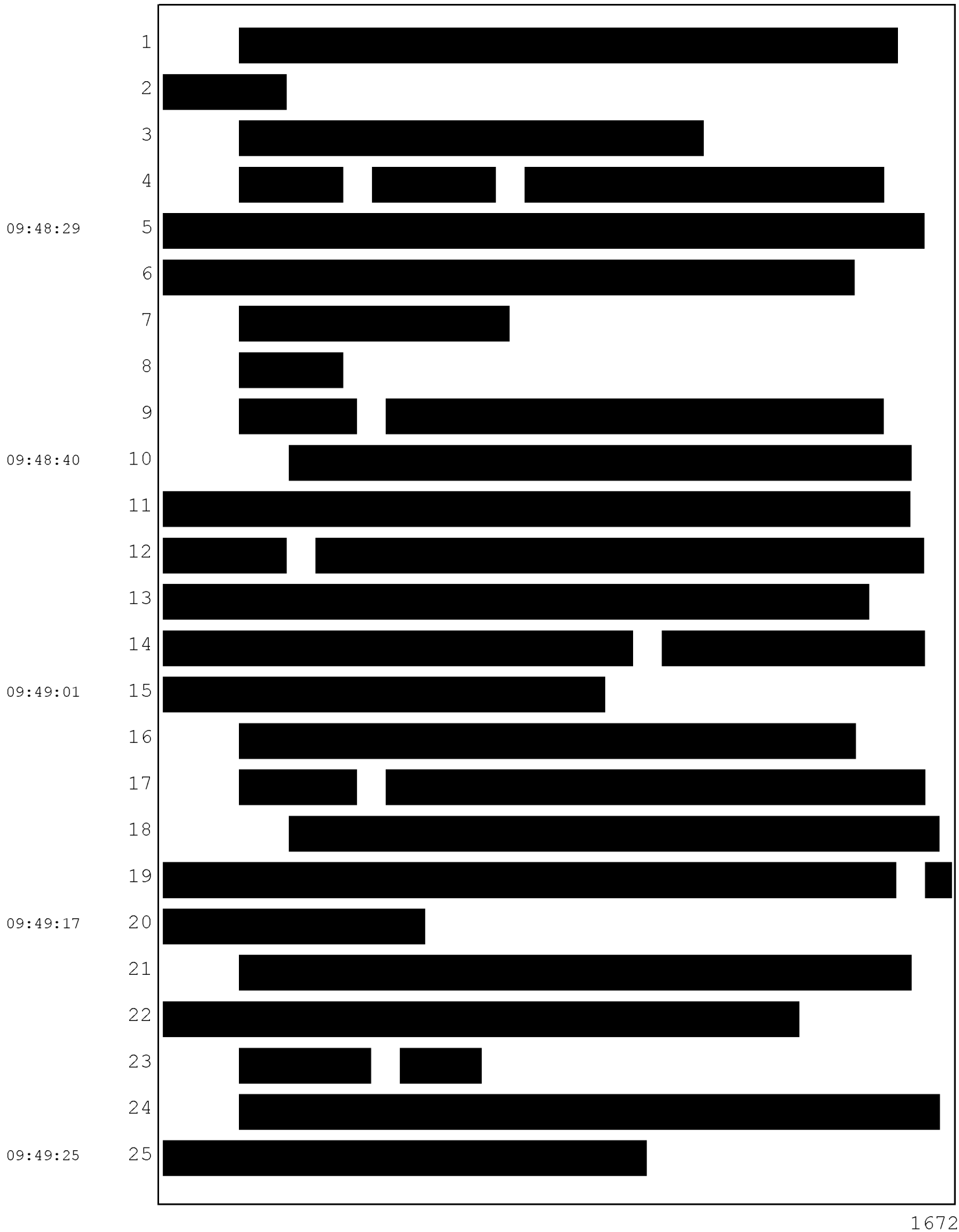
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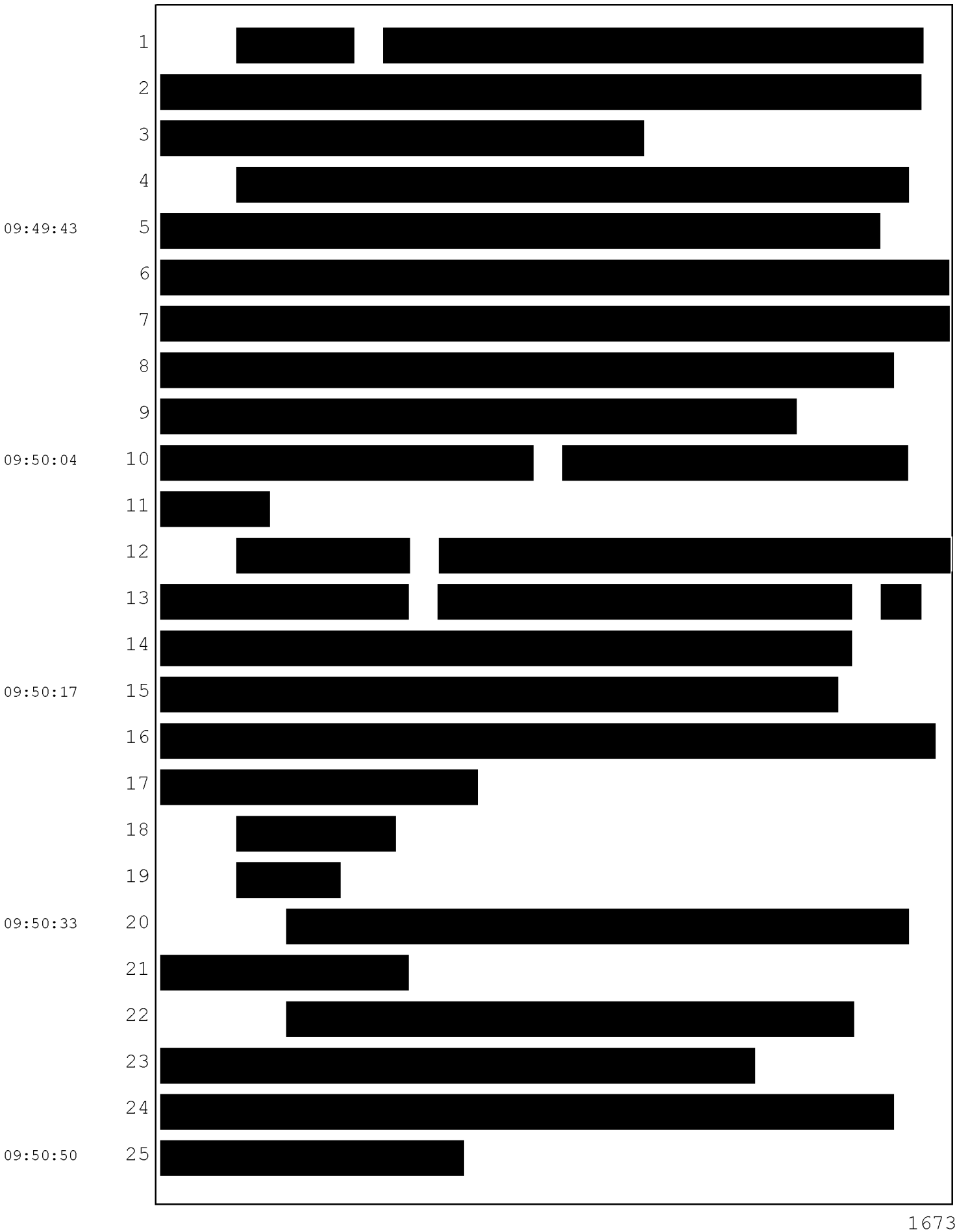
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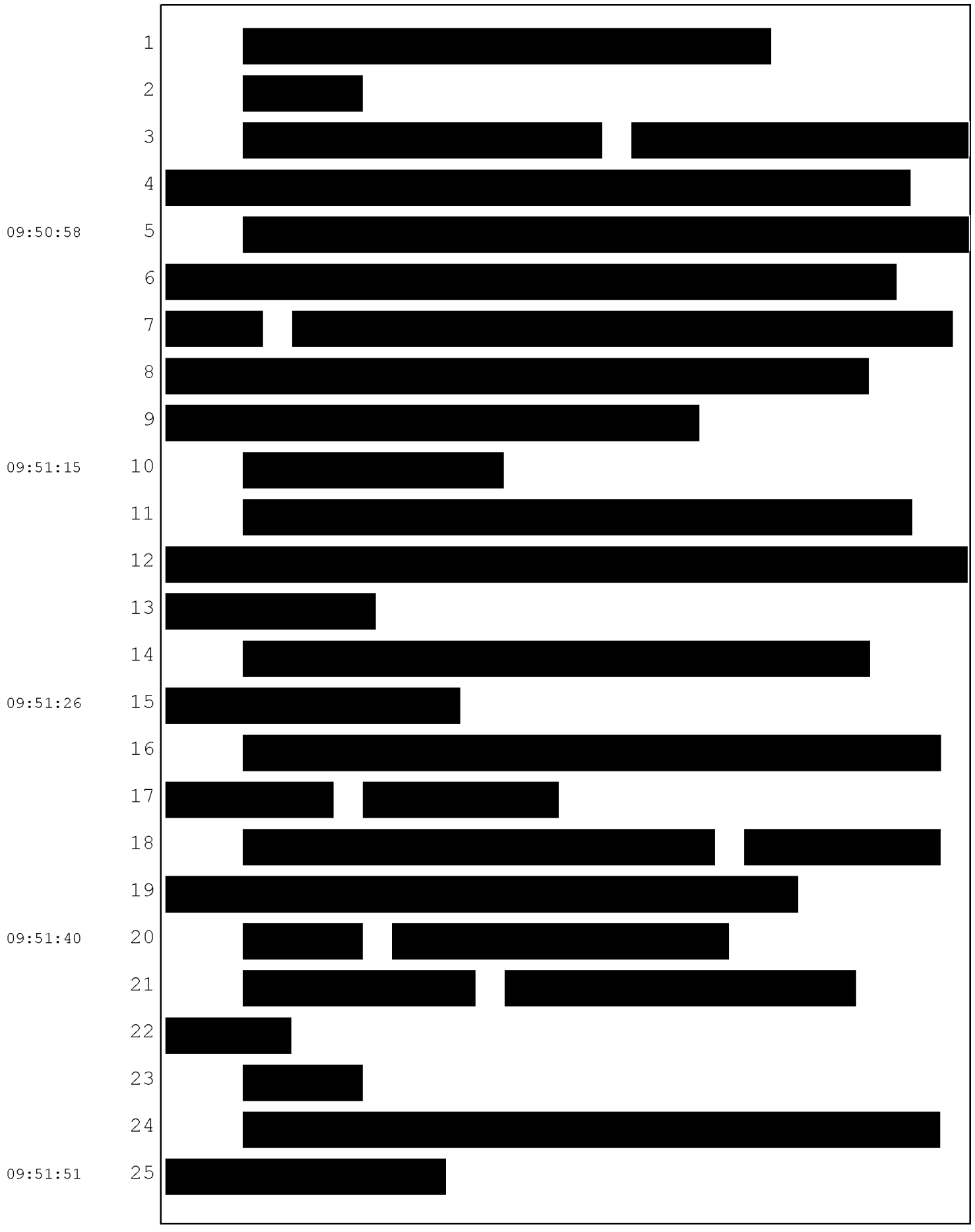
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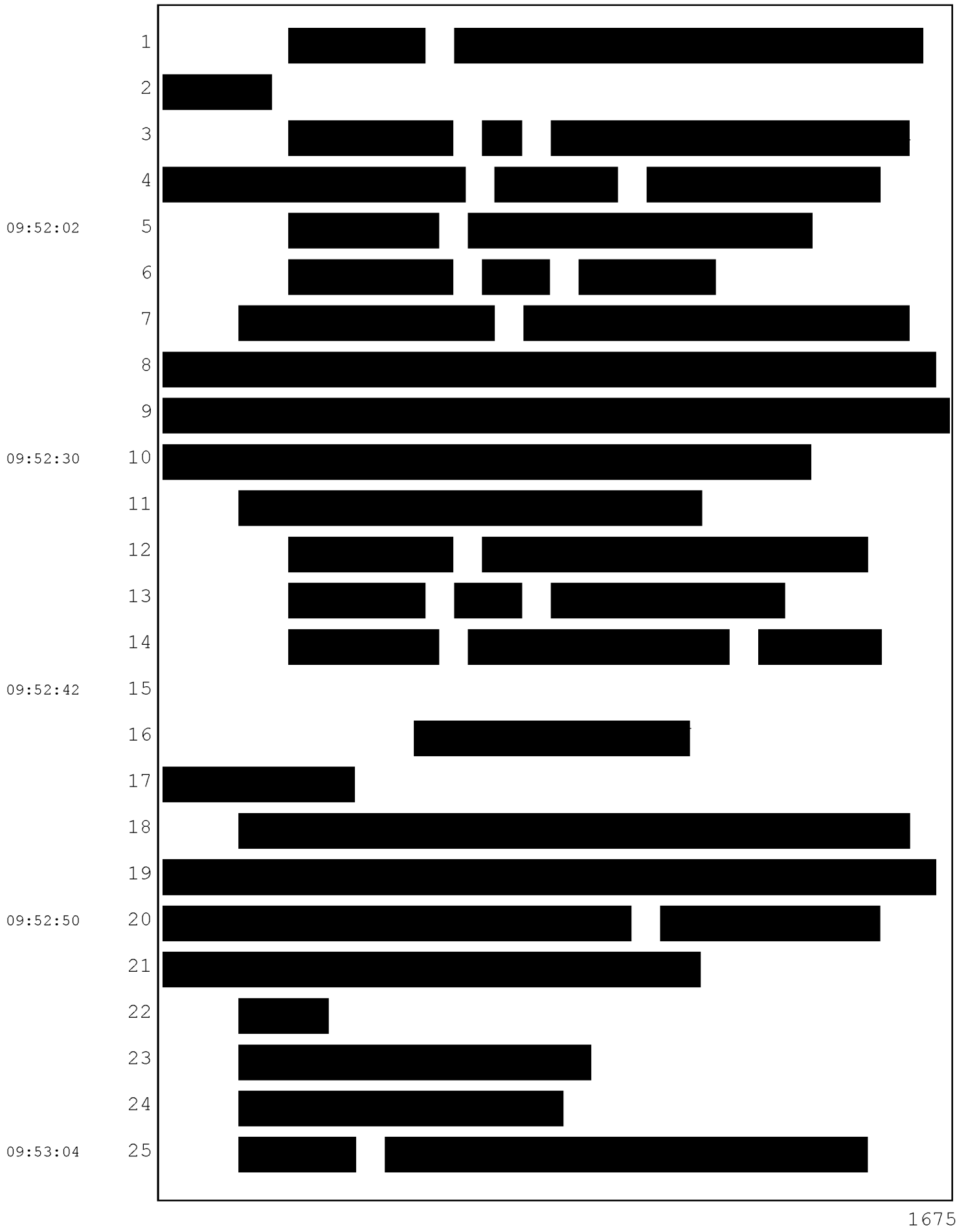
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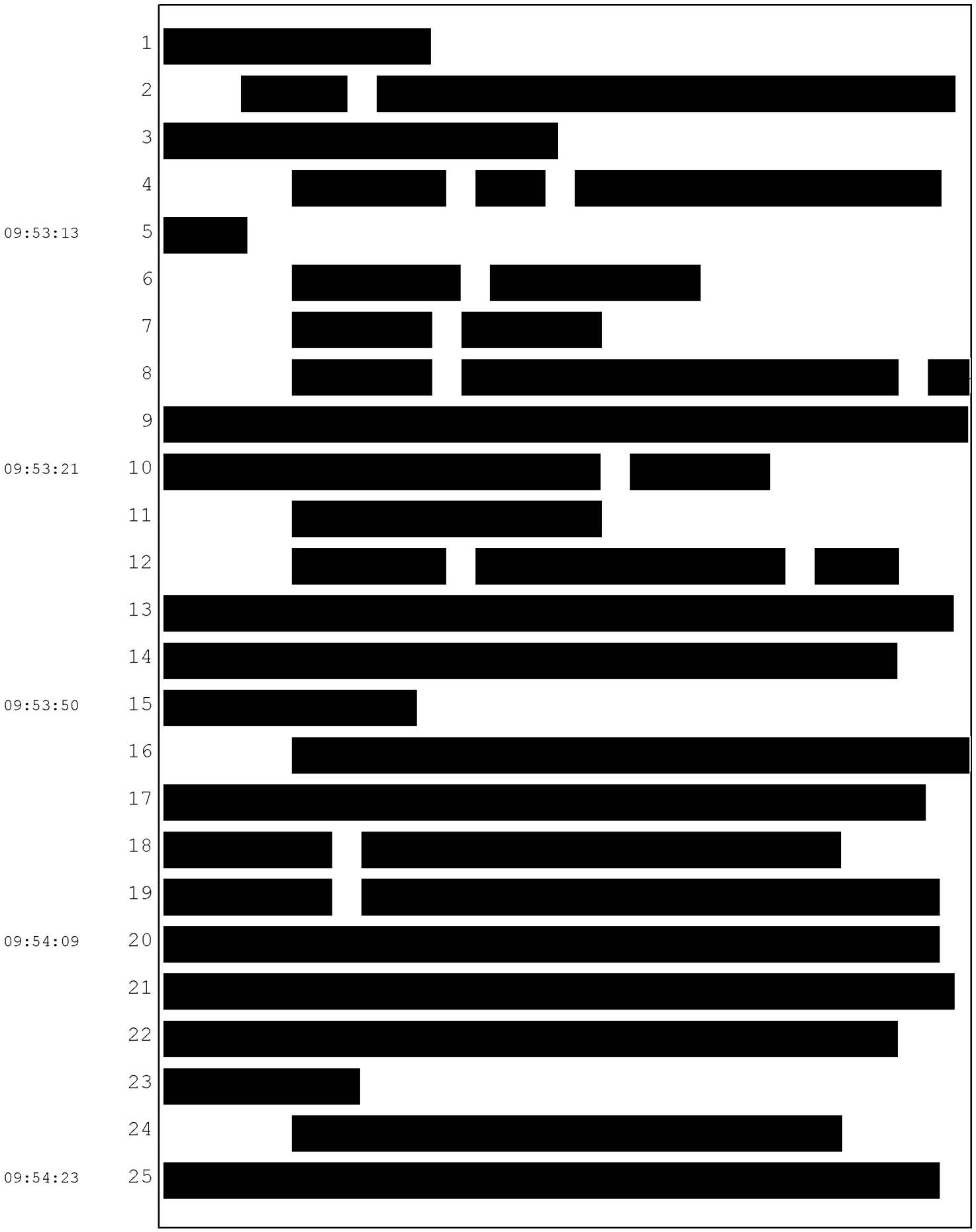
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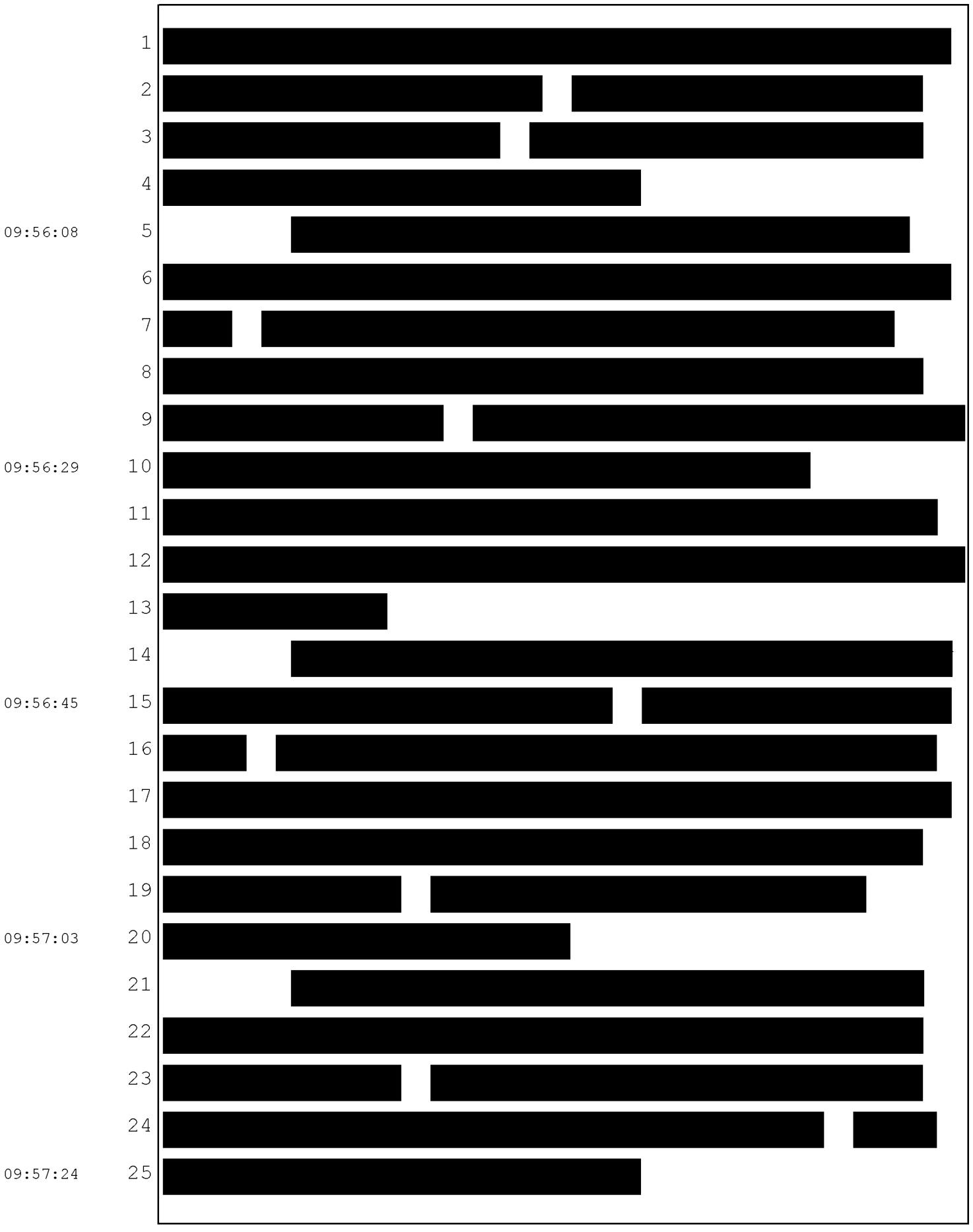
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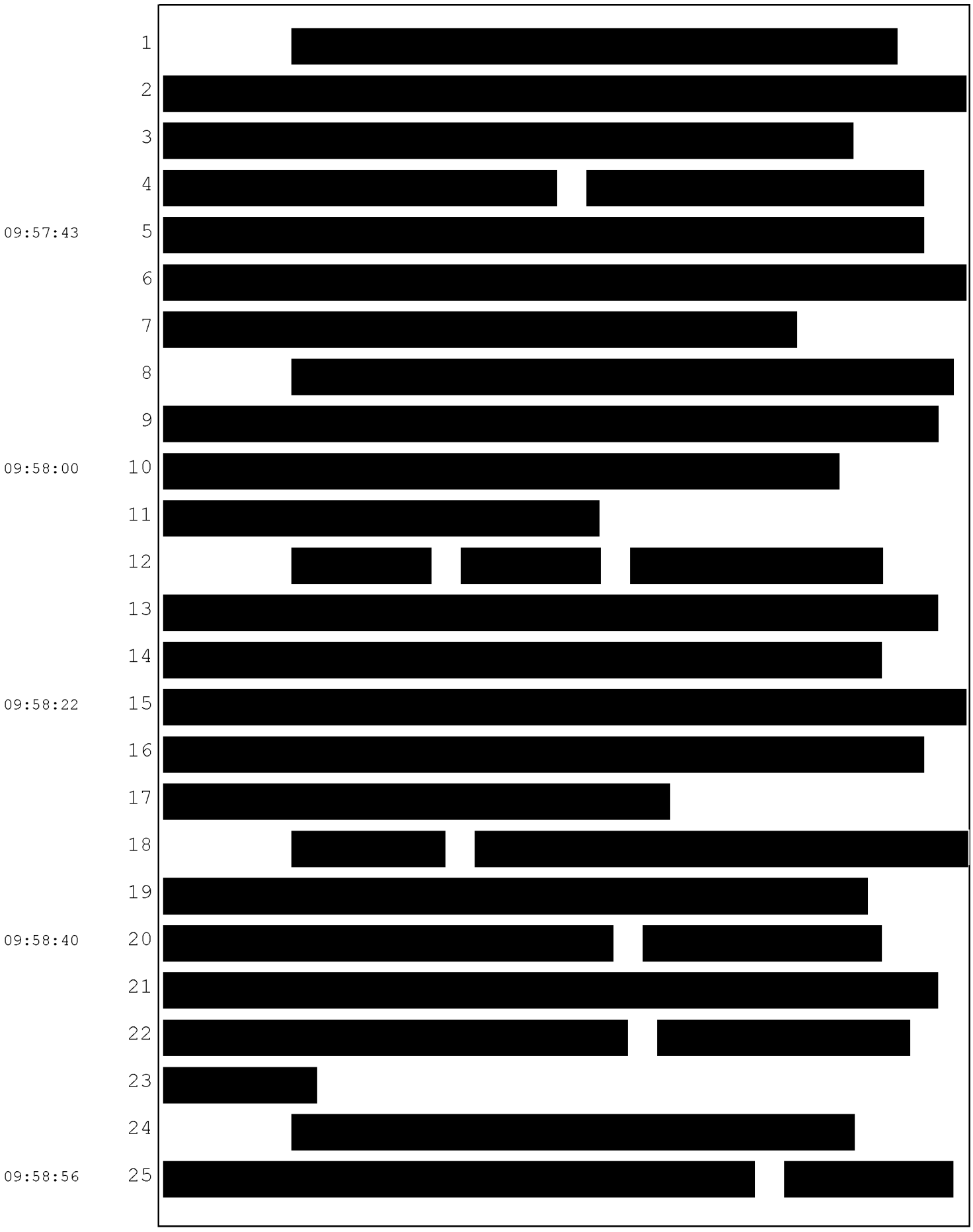
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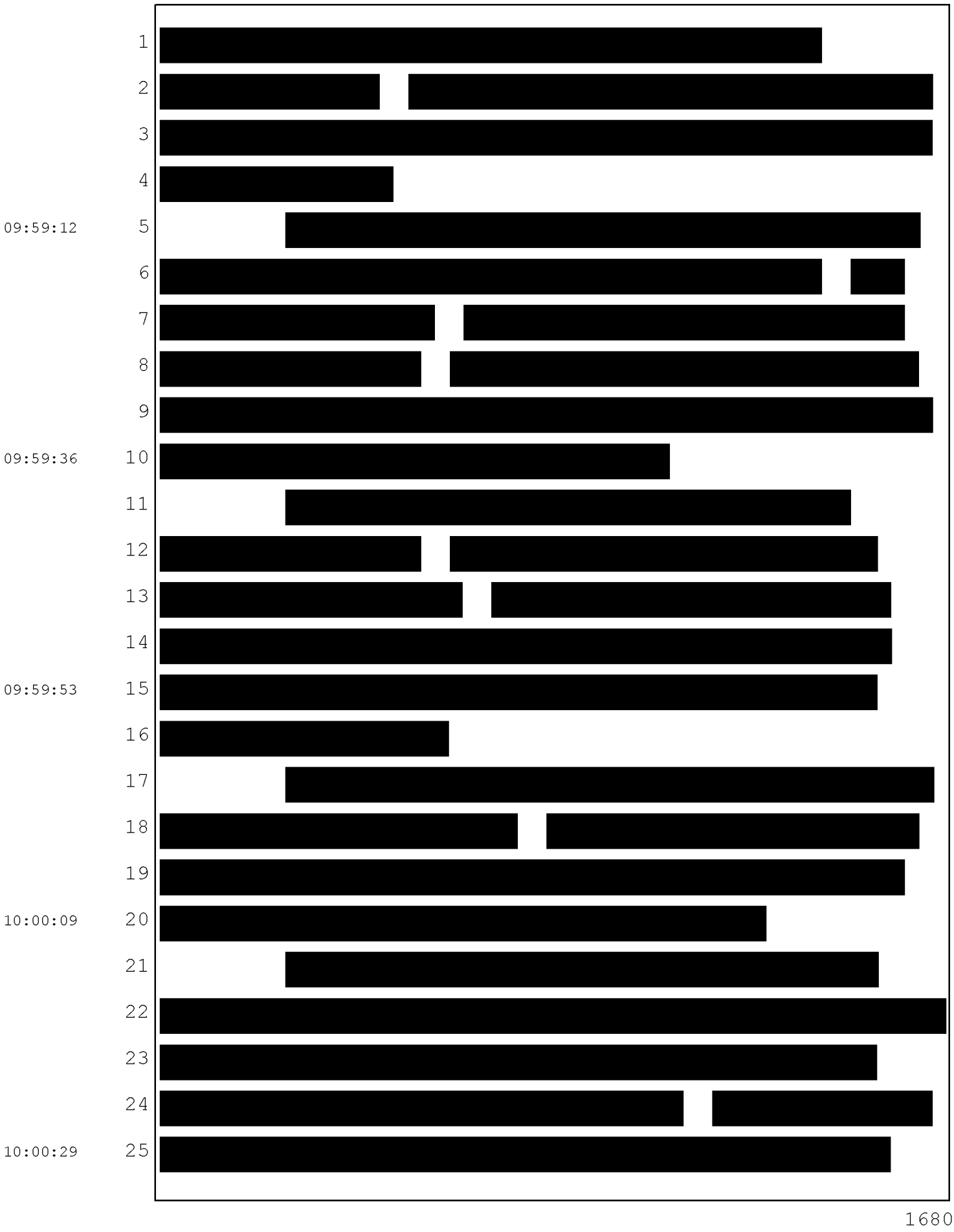
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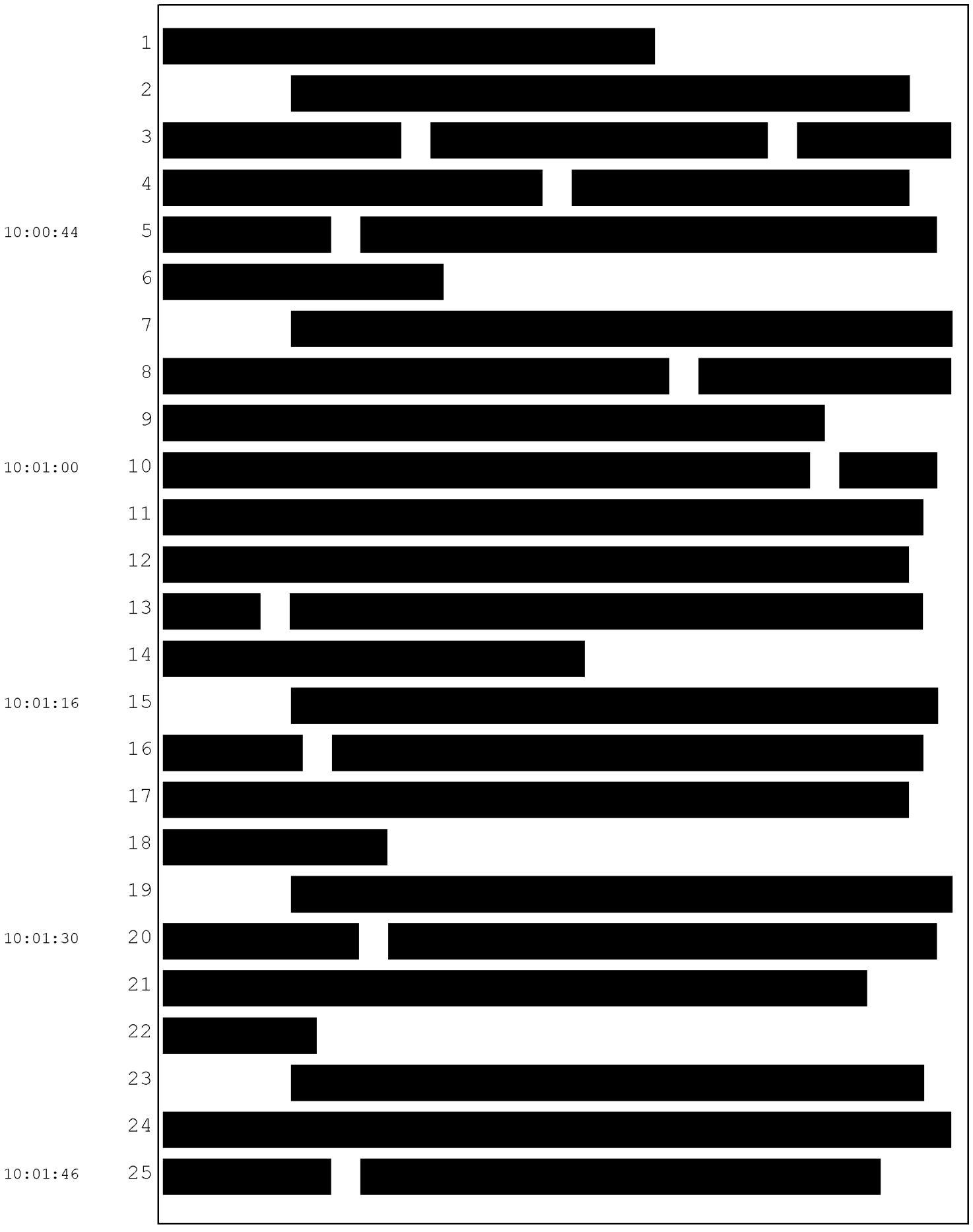
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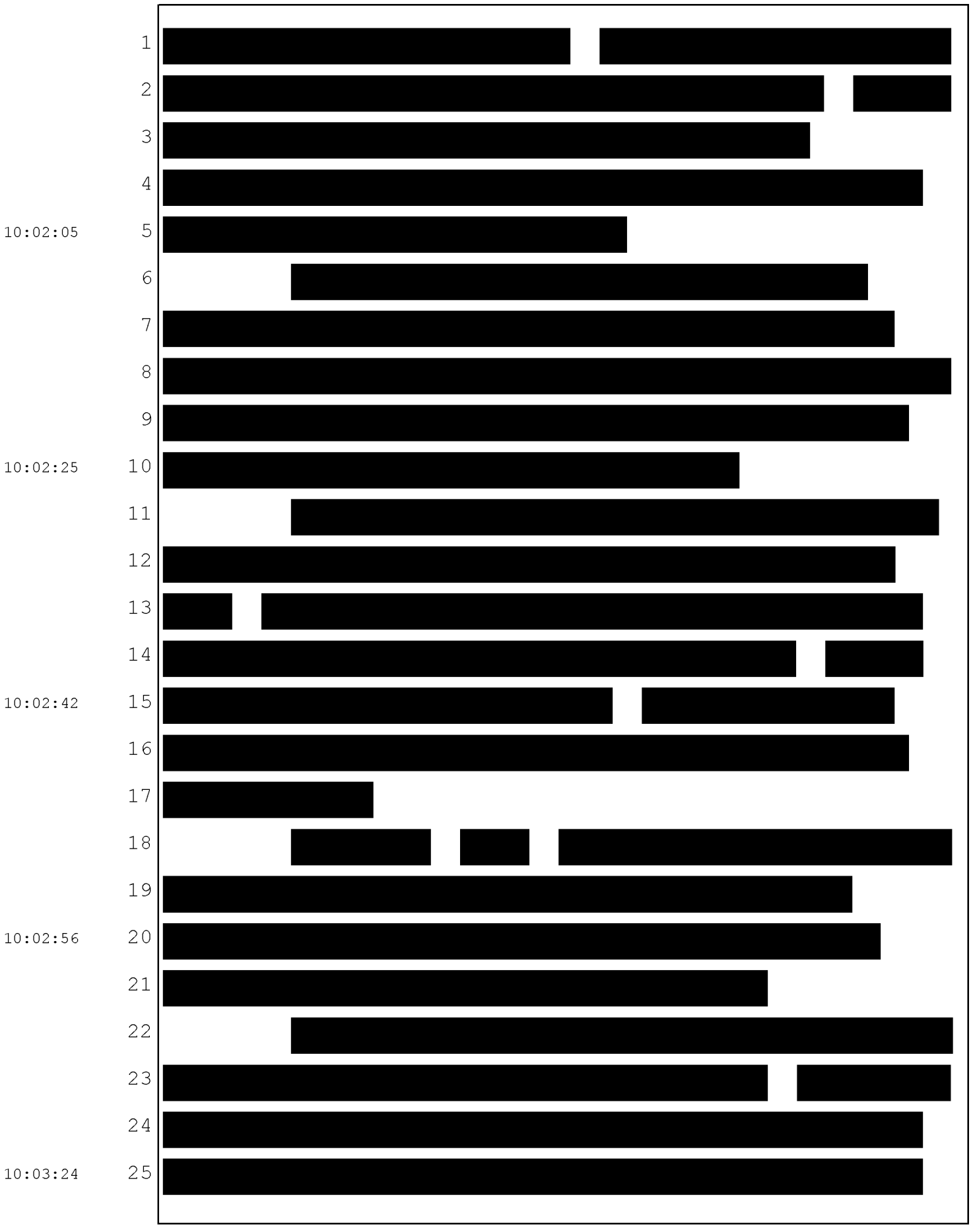
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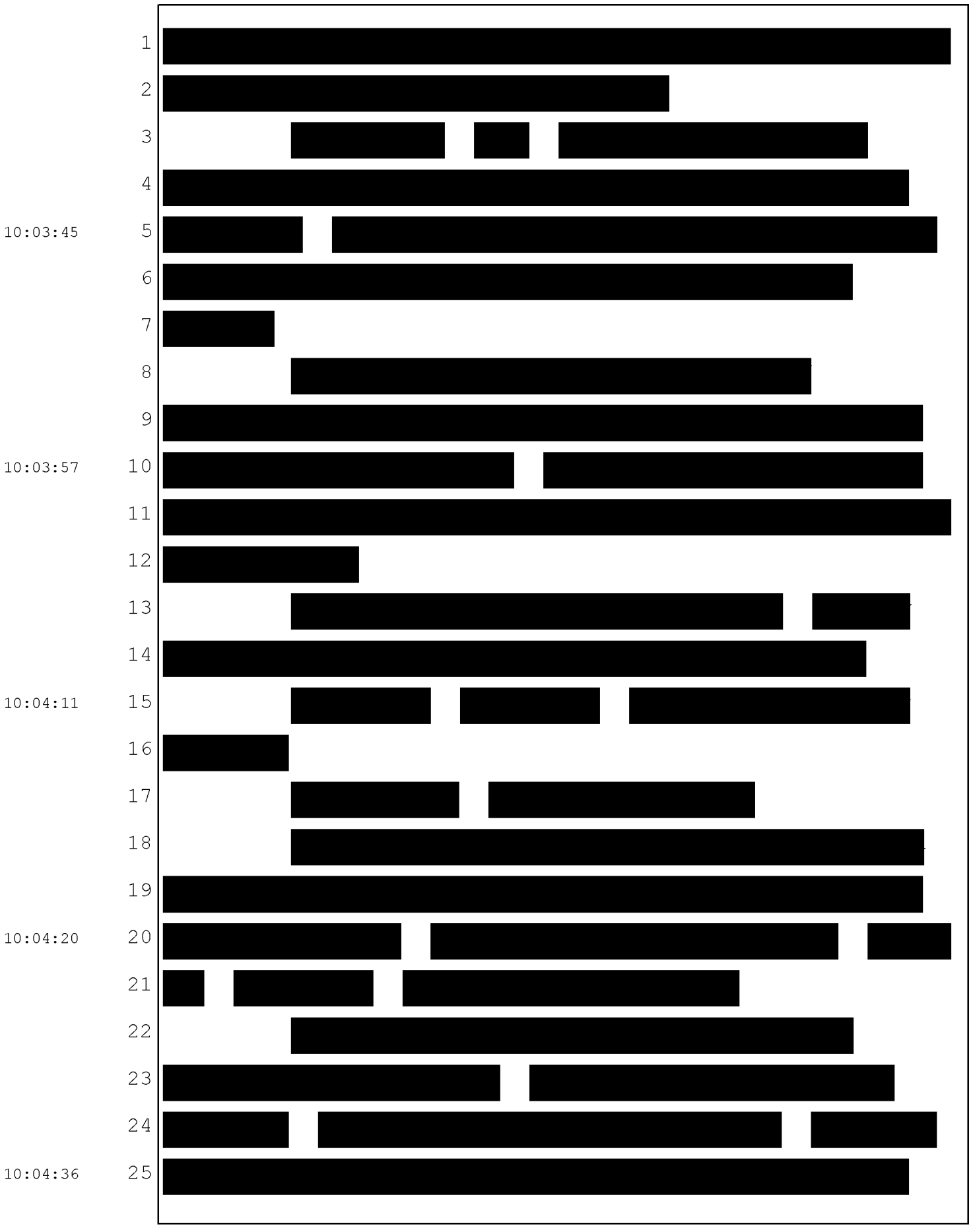
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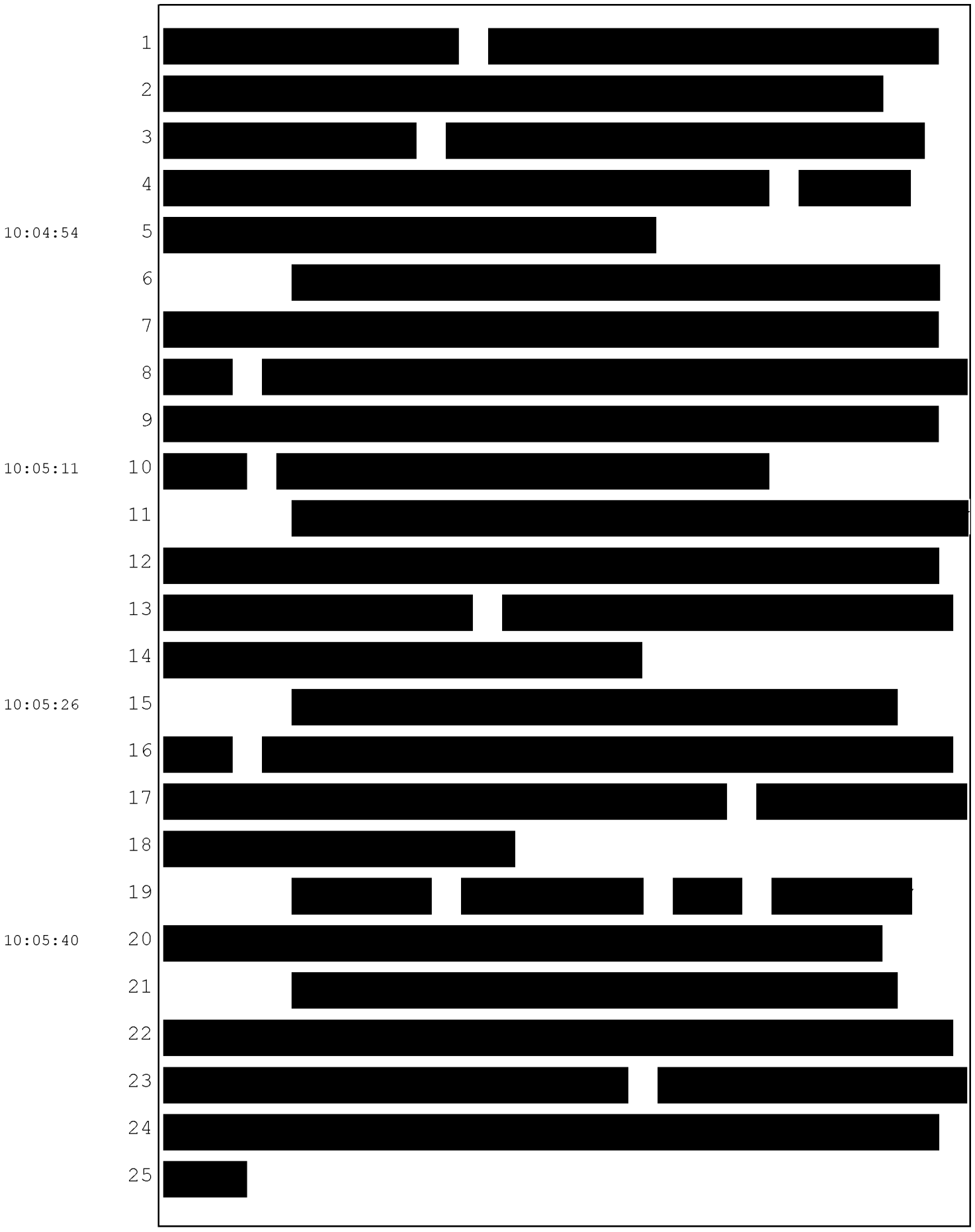
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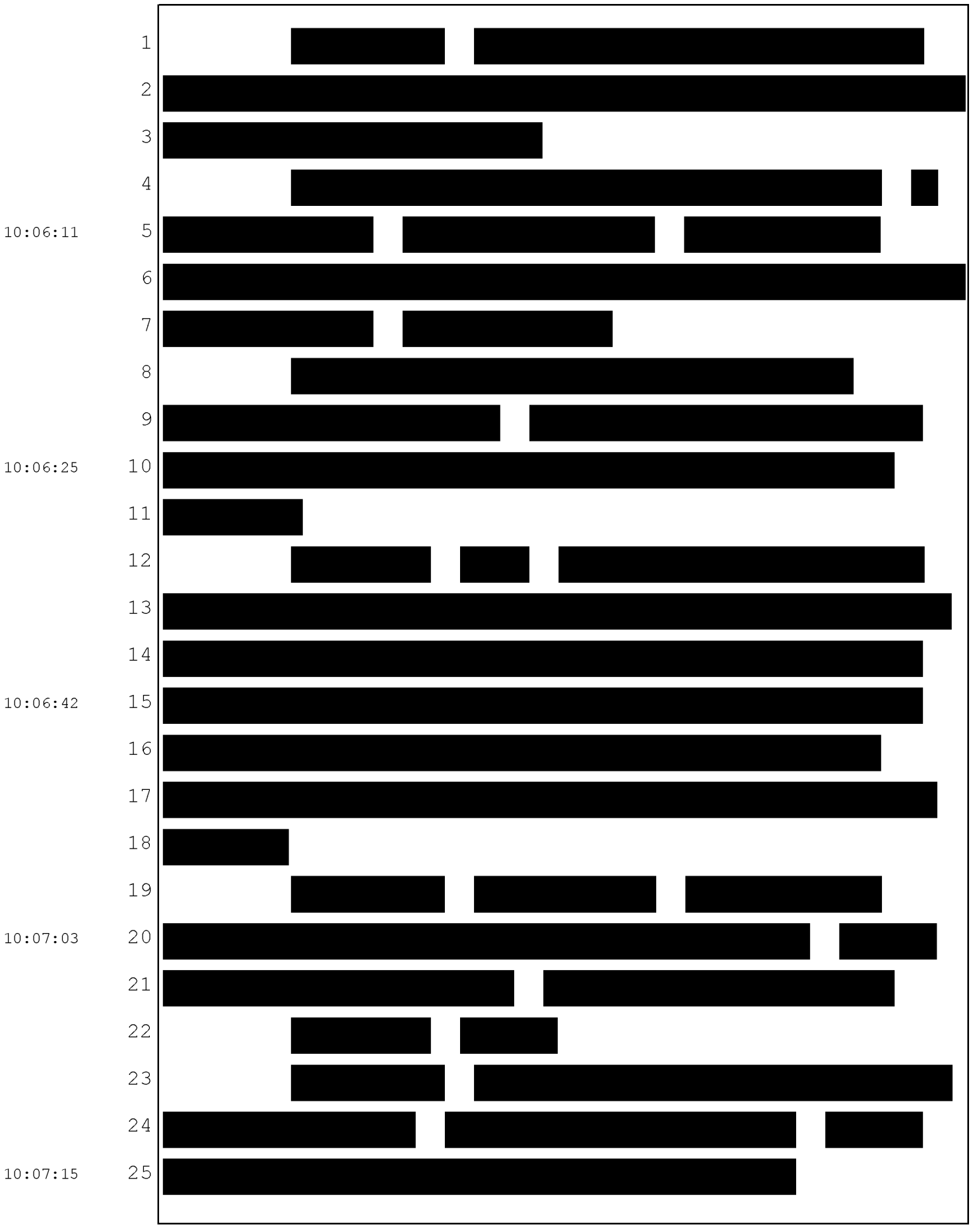
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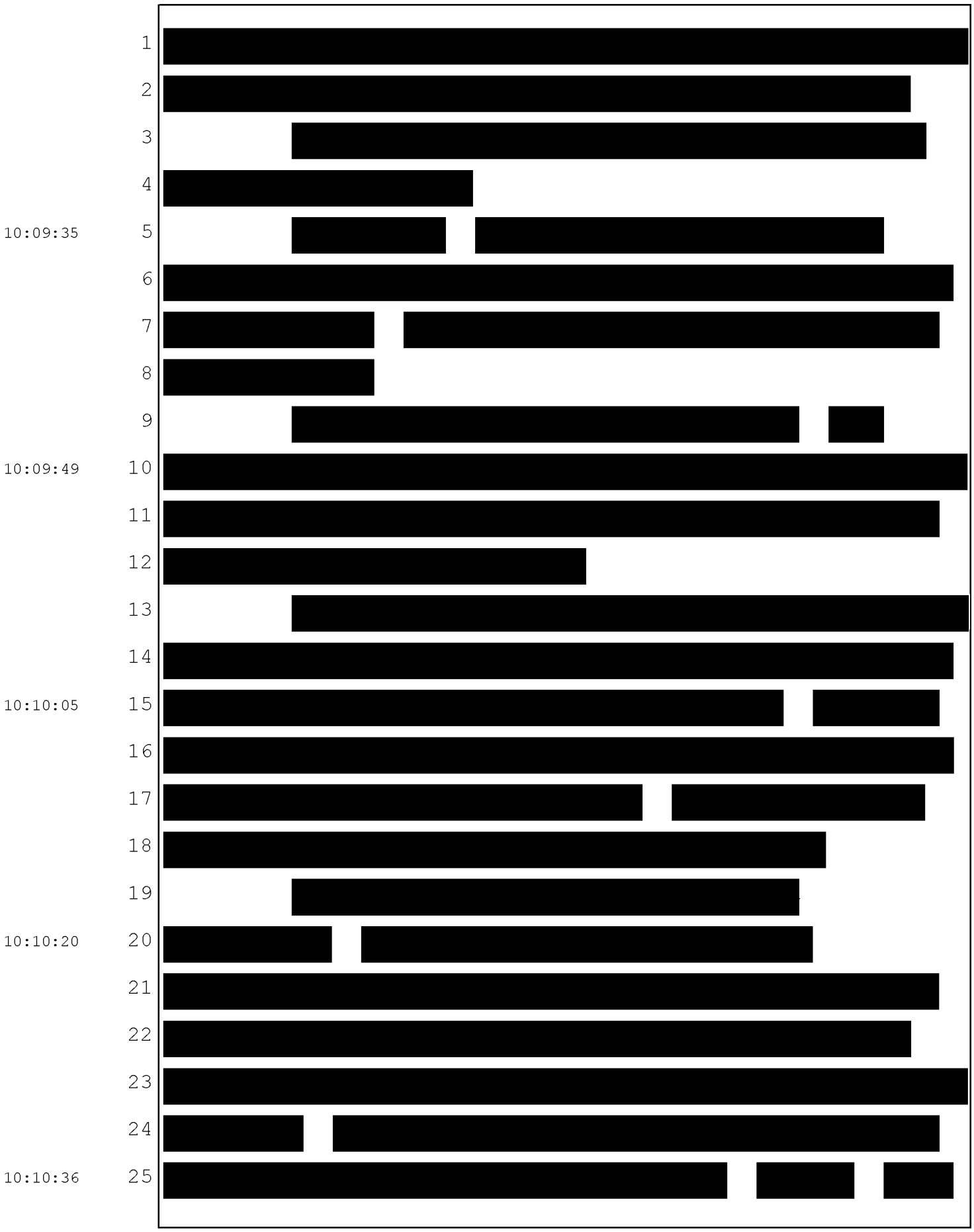
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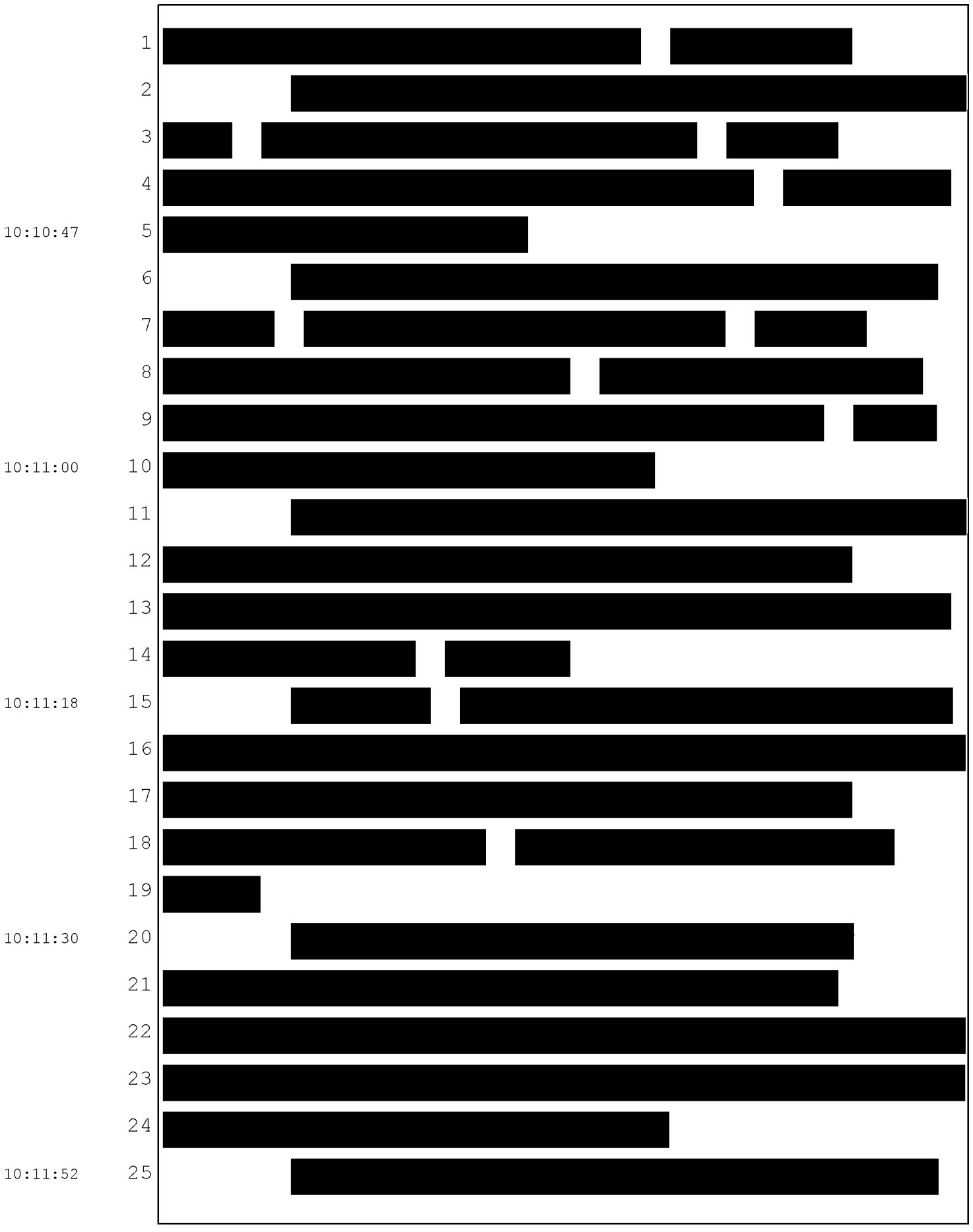
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[redacted]

(Jury enters courtroom.)

THE COURT: Good morning, Ladies and Gentlemen, and welcome. Thank you very much for your patience. As I'm sure you can see, we had to have a short hearing and have a discussion outside of your presence, but I promise you that all of our work that we're doing here is not intended to keep things from you. In fact, quite the opposite. We're trying to streamline things to make sure that everything proceeds smoothly.

So now we're getting -- we're ready to get started. And Mr. Dickens or Mr. Wisner, you may call your next witness.

MR. WISNER: At this time, your Honor, we call

Dr. Christopher Portier to the stand.

THE COURT: Very well.

Good morning again, Dr. Portier. If you could please return to the witness stand.

10:16:33 Ladies and Gentlemen, Dr. Portier was put under oath earlier this morning, and he remains under oath at this time.

And Mr. Wisner, when you're ready, you may proceed.

DIRECT EXAMINATION

BY MR. WISNER:

Q. Good morning.

A. Good morning.

10:16:56 Q. How are you doing today?

A. A bit nervous.

Q. Okay. I understand you don't live in the United States. Where are you coming from?

A. Switzerland.

10:17:04 Q. How's the jet lag?

A. It's okay.

Q. What time did you wake up this morning?

A. 4:00.

Q. All right. Dr. Portier, could you please

10:17:12 introduce yourself to this jury? Tell them a little bit

about your educational background.

A. Okay. I'm Christopher Portier. I'm from Louisiana, not Switzerland. I have a Bachelor's degree in mathematics with a minor in computer science. I went
10:17:32 to the University of North Carolina for graduate school, where I got a Ph.D. in biostatistics with an emphasis on epidemiology. My Ph.D. thesis was on the design and analysis of animal cancer studies.

Q. Did you also do a Master's thesis?

10:17:52 A. Yes, I did a Master's thesis. That was on designing an epidemiology study to look at the potential impacts of electric and magnetic fields from power lines on childhood leukemia rates.

Q. And just to be clear, just to define a few of
10:18:12 those terms, what is epidemiology?

A. So epidemiology is the study of human populations and the relationship between -- the association between exposures to the population and disease.

10:18:22 Q. So in the context of the power lines and leukemia, how would that work?

A. Well, there was an article in the literature, paper, that had just come out, where they looked at distance to power lines, and they looked at children that
10:18:37 had childhood -- that had leukemia and how far they lived

from the power lines. And then they looked at other children who, sort of, matched those in terms of many things, like age and parents' social, economic, education status, and they looked at how far they lived from power
10:18:55 lines and were able to show a relationship.

And so what I did was to design a study to both replicate that and improve upon it.

Q. After your education from UNC, what did you do for a living?

10:19:10 A. I was -- my Ph.D. was done while I was a special fellow with the National Institute of Environmental Health Sciences in North Carolina. And when I finished my Ph.D., they hired me into a permanent position as a research scientist at -- I'll say NIEHS. It's easier
10:19:32 than National Institute of Environmental Health Sciences every time I say it.

I had two jobs there. One was to do research on the statistical analysis of all kinds of experiments in toxicology. Not just cancer but developmental and
10:19:49 immunological studies. And then I was to work with the national toxicological program, which had just been moved to NIEHS, and help them with some of their analyses of their studies.

I did that for about five years, and then I got
10:20:04 much more interested in the basic science. And I was

able to develop my own laboratory, looking at computational biology and risk assessment, using some of these analysis tools to better understand human risks in human populations using computational tools.

10:20:23 Q. I'm just going to interject now, because we should ask questions as well.

Yeah, you said you opened your own laboratory. Was that external to the NIEHS, or was that within the research function of the organization?

10:20:43 A. So the NIEHS funds a lot of research. Some of it is inside the NIEHS, about 10 percent, and the rest is funded outside at universities and research centers all around the United States. This was internal to NIEHS, so I was what's called an intramural research scientist.

10:21:00 Q. And what sort of projects did you work on while you were at the NIEHS?

A. Well, on the research area, I did a lot of work on cancer. I did some work on immunotox. I did some work on genomics, genetics. These are looking at how

10:21:22 genes control the development of proteins and the chemicals that make your cells run the way they run. I had a lab that did that work as well. And I did some climate change work and some other stuff.

Other work I did for NIEHS, at some point,

10:21:43 probably 10 or 15 years into my career, I was the

recognized expert at NIEHS on risk assessment issues. And they were routinely tasked with risk assessment related issues, and I would get tasked with those for the institute.

10:22:00 Three that stand out for me was when the United States and Vietnam were normalizing relationships -- for years they wouldn't talk to each other -- Congress wanted to see a research program between Vietnam and the United States on herbicides that were used during the Vietnam

10:22:22 war. And so they tasked me with going there, working with the Vietnamese to set up such a program for both health and exposure issues.

Q. And were you looking specifically at cancer there as well?

10:22:30 A. We were looking at cancer and birth defects. Both of them were very important attributes.

The second one would be, by my luck, power lines and childhood leukemia. It turned out by this time that there were about 20 epidemiology studies on the topic, and it had created a considerable stir, and so there was a special research program put together that NIEHS was in charge of, the Rapid Research Program.

And I was part of that research program, but at the end of that research program -- they spent

10:23:07 $65 million over five years -- I was tasked with taking

all of that research and doing a risk assessment on behalf of the government and submitting that to Congress, which we did.

We found them to be possible human carcinogens, but not that strong of an evidence, but there was some.

Q. Doctor, before you move on, just to be clear, as you looked at this full body of evidence, had your opinion about power lines and leukemia changed from the time of your Master's thesis?

A. Oh, definitely, because my -- at the time of my Master's thesis, there was only the one epidemiology study. By the time we were looking at the evidence from the research program, there were a thousand publications on it, not just epidemiology, but animal studies, mechanism-based studies, looking to see why this is happening at cellular level and things like that.

So, yes, of course my opinion changed because the science changed.

Q. And just to be clear, in your entire experience working at NIEHS and looking at these health risks, did you ever just rely on one study?

A. Oh, no. You would never do that. That would be inappropriate to look at the literature. You really want to look at everything when you're doing a risk evaluation.

Q. At some point you were elevated to the director of the Environmental Toxicology Program?

A. So that was the third thing, yes. So in 2000, I was made director of the Environmental Toxicology Program, which basically was the person in charge of all toxicology science inside the NIEHS, and then I was also made the associate director of the National Toxicology Program, which in essence you direct because the director of that program is also the director of NIEHS. And he's got other things to do, and so he lets the associate director run the whole program.

So basically I was in charge of all toxicology at NIEHS, and in that capacity I looked at a lot of different risk assessment issues for them.

Q. Are you familiar with something called the Report on Carcinogens?

A. Yes. The Report on Carcinogens was part of the National Toxicology Program. It was my responsibility as the associate director to make sure the program ran right and the decisions from that program were reasonable.

The Report on Carcinogens creates the Department of Health and Services in the United States official list of what are carcinogens and what are not carcinogens.

Q. To be clear, that's a distinct agency from the Environmental Protection Agency; is that right?

A. That is correct.

Q. And at any point -- well, what are some of the projects that you worked on as the director?

A. At the ETP?

Q. Yes.

A. Environmental Toxicology Program.

Well, we updated the rules for reviewing carcinogens for the Report on Carcinogens. Science changes over time and so you have to look at these rules and make sure they're up to date with the science.

10:26:18

I changed the direction of the National Toxicology Program. Up until my tenure there, mostly what they did was they'd take rats and mice and expose them to chemical and measure a bunch of things in the rats and mice, and then they'd do some studies in cells to see what was going on and figure out why it was happening.

10:26:35

By the time I was there, the science was really beginning to change. There were ways in which we could do the science which were completely different than what we'd been doing, and I asked myself if I was given the money to build this program today, how would I do it? And I said, well, this is not what I'd have.

10:26:50

So we put together a roadmap to change the program, focusing more on predicting human response than

10:27:05

observing animal response. And so the program now uses a lot of high-throughput robotics screening techniques with human cells and fancy little organs that you can build from different cell types on a chip, and so that was one of the things we changed.

10:27:26

Q. Did that lead to a reduction in animal testing?

A. It did, and hopefully it will continue to lead to reductions as we begin to better understand what these assays are telling us, these studies in cells.

10:27:42

Q. So PETA must love you.

A. We had a very good relationship with PETA while I was there, yes.

Q. All right. At any time did you leave the NTP and NIEHS?

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A. I left the NTP to become the director of NIEHS's science advisor. Basically I was tasked with doing things that were new for the institution: Building children's environmental health centers, looking at climate change in human health, things like that.

10:28:16

But after doing that for three, I think, or four years, I got offered the position as director of the National Center For Environmental Health at the Centers For Disease Control and Prevention and also the director of the Agency for Toxic Substances and Disease Registry,

10:28:33

which I will call ATSDR, at the same time, which is also

at CDC. So it's one of these two jobs at one time.

Q. Did you get paid twice for that?

A. No, definitely not.

Q. All right. While you were in that position, did you work on any sort of human health issues like -- did you work on any human health issues?

A. Many. NCEH, the National Center for Environmental Health, is the chief Public Health agency for environmental issues. So they have programs on lead poisoning prevention, asthma prevention, climate change in human health, air pollution in human health, things like that.

They also do a national survey every two years of -- they take blood samples from people around the United States and they measure roughly 300 different chemicals in blood and urine, and they track them over time to see if the exposures are going down or going up and whether they should be concerned.

ATSDR, there focus is what are called Superfund sites. These are areas where pollution, chemicals and stuff have been left, and the company's either gone or it's been discovered, but it looks like it's potentially toxic to humans.

ATSDR went in, evaluated the sites, figured out if it was a risk to humans, and then EPA was tasked with

cleaning it up and suing whoever caused it.

So they create these things called tox profiles, which are basically a review of all the science on chemicals that appear in toxic waste dumps, Superfund sites, and they also do epidemiology studies and other things.

Q. And while you were at the ATSDR and you were a director of that, were you ever asked by the EPA to not investigate a chemical substance?

10:30:44 A. No, not in my -- not in my tenure there. I was at NTP, but not at the CDC.

Q. Did you ever leave that joint position, sir?

A. Yes, I did. In 2013, I retired from working for the US Government.

10:31:05 Q. And is that when you moved to Switzerland?

A. Yes. My partner lived in Switzerland. We'd lived across an ocean for 12 years. We decided it was time to get married and live together since I was retired now.

10:31:21 Q. Since retiring, have you stopped doing work in the scientific field?

A. No, definitely not.

Q. What have you been up to?

A. I work -- well, first, I -- right after I

10:31:32 retired, I went to the International Agency For Research

on Cancer for six months, did a research issue there looking at how to review mechanistic data in evaluating cancer findings. We wrote a paper from that.

And then after that, I worked for the Environmental Defense Fund here in the United States. They're a non-government organization, and what they do is they actually pay for scientific research and they work towards having science appropriately used in policy decisions. So they push very much for good science in policy decisions. And with them, I've been doing some epidemiology studies and other things.

Q. I understand, Doctor, that you've actually been doing an epidemiology study here in the Bay Area; is that right?

A. That's correct. One of the first tasks I did with EDF and their chief scientists was the meet with Google because we had this idea that Google streetcars could be equipped with environmental air pollution monitors and drive around and see what kind of data we could collect and whether we could use it in evaluating health issues.

They agreed, and because they have to -- they have to maintain these cars, they wanted it somewhere in the Bay Area. We decided Oakland was the best place to do it.

So we drove around Oakland for two years -- I think it's about 3 million measurements taken in the Oakland area -- built an entire picture of air pollution at the local level in Oakland, and then we worked with 10:33:14 Kaiser Permanente here in California to look at the health effects related to those exposures to the people in Oakland, and we were able to show health effects blocks apart, different -- different health risks in Oakland by going two blocks or three blocks away.

10:33:30 That's now expanded to the whole Bay Area. We're doing driving all over the place with six cars now.

Q. So through this study in epidemiology, you're going to be able to tell us, you know, which blocks have cleaner air than others; is that right?

10:33:46 A. No, because -- because there are rules that -- that don't allow us to do that because it could tell you something about individual people's medical conditions, and so there will be some rough maps. I don't think we can do block by block. We can do that, but we can't 10:33:59 present that.

Q. I have an address for you -- no, I'm just kidding.

All right, Doctor. I want to go through some other credentials. I know we've been talking about this 10:34:09 for a while, but I think it's important.

Have you ever been a -- have you ever served on any committees?

A. Oh, dozens.

Q. Let's talk about a few of them. Chair of the subcommittee on toxics and risks of the President's National Science and Technology Council. What is that?

A. So the President's National Science and Technology Council is made up of heads of various agencies, and under that are subcommittees that deal certain issues. There's probably 15 or 20 different subcommittees.

The subcommittees -- the subcommittee on risk that I was the chair of was basically looking at EPA, FDA, CDC, NIH, in how they calculated, looked at risk, trying to make the agencies work together and in a common way in looking at these issues.

I also served on the emergency response subcommittee for that, but just served on it.

Q. Are you familiar with an EPA Science Advisory Panel?

A. The EPA Science Advisory Panel is mandated in the law. There's a law called the fungicide insecticide and -- FIFRA, Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA. And it requires EPA to have a group of scientists who advise them on the way in which

they are evaluating pesticides.

The members of the SAP are not chosen by EPA. They come in nominations from NIH and from the National Research Council, the National Academy of Sciences.

10:35:55 There are eight members on the SAP, and I served on the SAP for five or six years and I was chairman for about three to four years.

Q. And in that capacity as chair or as a member of the EPA's Science Advisory Panel, did you advise the EPA

10:36:14 about whether or not their assessments of particular chemicals were accurate?

A. Yes and no. Most of the things they brought to the Science Advisory Panel were broad things. How to look at children in terms of chemicals. But they also

10:36:34 brought either specific chemicals or classes of chemicals.

So acetylcholinesterase is an important target for pesticides. It's a neurotransmitter, and if you block it the pest dies. But there's many of them, and so

10:36:51 the question is: If humans are exposed to many of these things, how much of a problem will it be with humans?

And so they're trying to figure out how to do that analysis for common human exposures.

Q. And when you review an EPA assessment, would you

10:37:07 take a look at the science or just look at the

conclusions?

A. No. Of course, we'd look at all the science.

Q. And see if you agreed with the conclusions?

A. And see if we agreed with the conclusions. And many times, we did not, but EPA -- we were just advisory, and EPA would do what they want.

10:37:18

Q. The EPA, does it use like an advisory document or a guidance document on how it's supposed to view science?

10:37:30

A. Yes. EPA has a cancer risk assessment guidance document which tells them how to evaluate the literature and look at cancer risk in humans from that literature.

Q. Are you familiar with that document?

A. Very. I helped draft it.

10:37:47

Q. What do you mean?

A. When EPA put together that document, they asked several other Federal scientists to read it, comment before they went for public comments. And so I participated in that process with them.

10:38:02

Q. I understand you have also served -- you mentioned this earlier -- at the International Agency For Research on Cancer. I believe we call it IARC. What is IARC?

A. So IARC is a semi-independent agency of the

10:38:18

World Health Organization. It was created, I think,

50 years ago. The idea was to do cancer registries around the world so that you could find out how much cancer people were having in various countries to develop research programs in those countries to looking at cancer risks and then also to evaluate specific compounds as to whether or not they cause cancer in humans.

10:38:39

Q. We're going to talk about IARC quite a bit in a few minutes, and I just want to get through the rest of your credentials here.

10:38:54

You said you served on a six-month panel on the Agency For Research on Cancer. What was that panel about?

A. Six months, no. It was -- I was there as a visiting scientist.

10:39:05

Q. Oh, I see.

A. It was not a panel. I was doing research with members of IARC.

Q. And what were you trying to do there?

A. Looking at mechanistic information and seeing how to better organize it so that you can evaluate it in terms of looking at the risk of cancer. As we'll talk later, I know there's lots of different kinds of research once you start looking at mechanisms, and it's hard to get a grasp on it and figure out what goes together and what doesn't. And that's what we spent time looking at.

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Q. I understand you've also -- we'll move on from various committees or we'll be here all day.

I understand you've received some awards; is that right?

10:39:48 A. Correct.

Q. Outstanding Practitioner Award from the International Society for Risk Analysis. What was that?

A. It had to do with my body of scientific research in the area of risk assessment. They were giving me an

10:40:04 honor for having done quite a bit of work in that area.

Q. And I understand that you've received Paper of the Year awards twice from the Society of Toxicology Risk Assessment Specialty Section; is that right?

A. That is correct.

10:40:15 Q. What does that even mean?

A. So the Society of Toxicology is the principal society for toxicologists in the world, not just the United States. Every year they give the subsection on -- risk assessment, specialty section, is that what was it?

10:40:35 Q. That's correct.

A. Gives out an award to one paper as the paper of the year. We won that twice. The first one was a paper on dioxins. We'd done a beautiful study at looking at various types of dioxins and showing that they were all

10:40:55 giving you the same response. It was a very nice paper.

And then the other one was a paper we used genetic information to predict from cellular evidence 200 different human diseases all in one big picture. It's got some great graphics and pretty pictures. But it was a good paper.

10:41:17

Q. I like pictures, Doctor.

I understand you're a member of the -- I'm sorry, you are not a member -- you are a fellow of the American Statistical Association. What does that mean?

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A. The American Statistical Association elects fellows. It's an elected position. I think the rules say it can be one-third of 1 percent of the membership every year. And so I was elected as a fellow when I was 32 or 33.

10:41:50

Q. And then the International Statistical Institute. Are you also a fellow there?

A. Yes. And it's about the same thing.

Q. The World Innovation Foundation, what's that?

A. It's a collection of scientists who provide comment on big public issues where science can potentially play a role. And so I'm a fellow of that. It's again an elected position. And it's unpaid. It's not a great big organization. It's just when need be, we get together and provide comment.

10:42:04

10:42:25

Q. What is the Ramazzini Institute?

A. So the Ramazzini Institute is an organization in Italy. It's funded primarily by contributions from people who live in Italy, the public give money to that institute. It's named after -- I forget his first name, but the last name is Ramazzini. He lived in the late 1600s, early 1700s. He wrote the first definitive book on occupational exposures and disease, giving some very good advice how to avoid disease in certain occupational settings. And so its focus is occupational and environmental risks.

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10:43:11

Q. Does that involve epidemiology then?

A. Yes, and toxicology and everything.

Q. All right. We mentioned two of your papers that won awards. I have here that you have over 250 peer-reviewed scientific papers, book chapters, and technical documents on topics in toxicology and risk assessment; is that right?

10:43:24

A. That's correct.

MR. WISNER: One moment, your Honor.

10:43:39

(Interruption in proceedings.)

MR. WISNER: May I approach, your Honor?

THE COURT: Yes.

Q. BY MR. WISNER: All right. Doctor, let's get into why you're actually here today, specifically to talk about glyphosate and Roundup. Before I do that, I want

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to sort of understand: Have you ever testified in court in front of a jury before?

A. No.

Q. Have you ever been an expert outside of Roundup before?

10:44:25

A. No.

Q. So this is your first. How did you get involved in this?

A. In March of -- well, in 2014, I was asked by

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IARC to serve on a panel that would review five pesticides, of which one was glyphosate, for their potential to cause cancer in humans. I was an invited expert on that panel. So what I was there for was to provide background expert advice to the people who were

10:45:03

on that Working Group, but I didn't participate in the decision discussion, nor did I participate in the writing of the document. I was there simply as -- to help with the science.

Q. And after that I understand -- we understand

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that IARC did classify glyphosate; is that right?

A. They did. They classified it as a probable human carcinogen. Should I explain that now or will we --

Q. We will get into that later. I just want to

10:45:34

clarify they did classify.

And after that, were you contacted to offer your opinions about the pesticide in litigation?

A. Yes, I was. I was -- I was contacted by a law firm to provide them advice on the science related to glyphosate.

Q. And low and behold, now you're here in court testifying.

A. Yes.

Q. All right, Doctor. Let's take a quick look at IARC and -- well, actually before you went to the IARC meeting and before you reviewed the literature prior to that, did you have an opinion about glyphosate?

A. No.

Q. Did anybody else, when you were there, have an opinion -- actually, I guess you wouldn't know. So I'll move on to my question.

All right. Let's talk about IARC. How are agents that are going to be reviewed by IARC selected?

A. So every five to six years IARC brings in roughly 20 to 25 outside scientists to look over a list of chemicals that they are considering putting on the report -- putting in their review process.

The chemicals they get are nominated by other scientists around the world, scientists within IARC, the public sometimes.

And so in 2012, I think it was, or 2013 or even '14 -- I just don't remember, it was before the IARC monograph on glyphosate -- they reviewed 200-plus chemicals and many of them were pesticides, and some of those pesticides got high recommendation for review and some got moderate and some got low.

10:47:21

And then what the IARC stuff does is try to find pesticides that it makes sense to put together because there are common studies or other things, and so that's what they do.

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Q. Do they just look at pesticides or all chemicals?

A. Well, they looked at all chemicals and radiation and other physical things and drugs and viruses. It's they look at virtually anything that can cause cancer.

10:47:48

Q. And one of the things that's come up earlier in this case is that, you know, IARC has only classified one substance as not likely carcinogenic. Is it fair to say that the majority of substances that IARC looks at they determine is a carcinogen?

10:48:13

A. No. No.

Q. Why not?

A. It's a small fraction of the -- well, they have different classifications for chemicals. There's known humans carcinogens, which is the highest level, and it's

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about 10 percent of the things they reviewed. And then there's probable humans carcinogens. It's just below that scale. And that's another 10 percent or so.

And then you've got maybe 15 percent. Then
10:48:41 you've got possible human carcinogens, a lower level. And that's about 30 -- 25, 30 percent. And then you've got a whole bunch of inadequates because there's just not enough data to make a decision or the data is so conflicting, you can't make a decision. And so that's
10:49:01 the bulk. That's 50 percent plus or minus of everything they've reviewed.

And I will point out that IARC doesn't review everything. IARC reviews things that are suspected of being carcinogenic to humans. It would be a waste of
10:49:17 money to review water for its carcinogenic properties. You don't want to spend time on things that are not likely to cause that effect.

Q. Fair enough. That was my next question.

So glyphosate was selected at some point, and
10:49:33 then it went up for review. I want to talk about some of the procedures of IARC.

Can you please turn in your first volume to Exhibit 166. What is this document, Doctor?

A. This is the preamble to the IARC Monographs on
10:49:59 the evaluation of carcinogenic risks to humans.

Basically this is their guidance document for the Working Groups that come in who review the data, this tells them how to do it, and it also puts rules on who gets to participate, who doesn't, and what their roles are.

10:50:17 Q. And this is the preamble that would have governed the glyphosate review at IARC; is that right?

A. That is correct.

Q. And does this appear to be a fair and accurate copy of that preamble?

10:50:36 A. Yes, it looks like it.

Q. Is this something you reviewed and relied upon in forming your opinions in this case?

A. Yes, to some degree. I mean, there are things in here that talk about -- well, I mean, I've certainly 10:50:53 read this document. I was involved in its development when IARC was making it. Many of the rules I use for evaluating evidence are also in here, but I don't use their categories and I don't use their classification scheme. I use a different way of putting all the 10:51:10 information together.

MR. WISNER: All right. Your Honor, at this time permission to publish Exhibit 166 to the jury.

MR. GRIFFIS: No objection, your Honor.

THE COURT: So are you moving then Exhibit 166?

10:51:28 MR. WISNER: Yes, I would like to move it into

evidence.

THE COURT: No objection?

MR. GRIFFIS: No objection.

THE COURT: All right. So Exhibit 166 then may be admitted and published.

10:51:35

(Exhibit 166 admitted into evidence.)

Q. BY MR. WISNER: All right. Doctor, on the screen, it's working. This is the preamble document we were talking about; right?

10:51:41

A. Correct.

Q. All right. I want to draw your attention to a paragraph and I want to get your opinion about it. On page 3 of this document, starting at line 6, it states: "The Monographs are uses by national and international

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authorities to make risk assessments, formulate decisions concerning preventative measures, provide effective cancer control programs, and decide among alternatives and options for Public Health decisions. The evaluations of IARC Working Groups are scientific, qualitative

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judgments on the evidence for or against carcinogenicity provided by the available data. These evaluations represent only one part of the body of information on which Public Health decisions are based. Public Health options vary from one situation to another and from

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country to country and relate to many factors including

different socioeconomic and national priorities. Therefore, no recommendation is given with regard to regulation or legislation, which are the responsibility of individual governments or other international organizations."

10:52:41

What does that paragraph mean?

A. Basically it says that IARC is trying to do the scientific decision of whether it's possible or not that this can cause cancer. But beyond that, in terms of how much cancer is going to be caused by a particular exposure level or how much is acceptable to your population, they don't comment on that issue.

10:53:00

Q. Does IARC recommend that a substance should be banned?

A. Oh, no.

10:53:14

Q. They leave that up to the governments to decide; is that right?

A. Yes, the classic example is DDT. Most western countries have banned the use of DDT, but in countries along the equator, where malaria is still a problem. But they -- most countries have regulations that allow use of DDT under specific conditions. And it's a known human carcinogen.

10:53:28

Q. And do -- are you aware of any organization or regulatory authorities that rely on IARC to help inform

10:53:47

their decision-making process?

A. Yes. There are numerous organizations that do that.

Q. Some in the United States as well; correct?

10:53:58 A. Correct.

Q. All right. I'm going to turn to another page here. Well, actually, I'm going to ask you some general questions.

I understand there's different participants at a

10:54:10 Monograph meeting; is that right?

A. That is correct.

Q. What is a Monograph meeting?

A. So what's a Monograph, first of all.

Q. Sure.

10:54:18 A. When IARC does one of these reviews, they produce a book, which covers all of the science and the reasons behind the decisions that are made in terms of the carcinogenicity of this particular substance. So that's a Monograph.

10:54:34 A Monograph Working Group is a group of scientists who are independent of IARC, not part of the agency, who actually review all this literature and come to that decision.

The process is -- starts about a year before the

10:54:48 actual -- there's a meeting of this Working Group that

lasts I think eight days generally. They all get together and they discuss this science in one of the four rooms. It varies. But about a year before that meeting, they start collecting the science. IARC does some systematic review to bring in papers for that science. They share it around, they draft some stuff, and then they have this meeting. And that's where they make the decisions and finish the Monograph.

10:55:09

Q. Doctor, would it be fair to say, then, that IARC makes its decision after they spent two days talking about glyphosate? Is that a fair statement?

10:55:25

A. No, no, not at all. It's a lot more effort than that, of course.

Q. And you know specifically about glyphosate because you were there and you participated?

10:55:40

A. That's correct.

Q. Now, I understand there's different categories of participants. There's the Working Group. My understanding is those are the individuals that actually vote at the end; is that right?

10:55:51

A. And write the document. That is correct. They have full responsibility for every word that's in that document and any decisions from that document.

An IARC Monograph Working Group decision is not IARC's decision. It's the Working Group's decision.

10:56:06

IARC just makes sure they follow the right process is all.

Q. And do Monographs or Working Groups have to be unanimous?

10:56:16 A. No, they do not.

Q. So there can be disagreement?

A. Correct. And sometimes that disagreement appears in the Monograph if somebody feels that strong about it, and other times, they don't feel strongly

10:56:29 enough that it matters.

Q. I understand there's also an invited specialist, which is what you were for glyphosate; is that right?

A. That is correct.

Q. And invited specialists are invited when

10:56:41 necessary to assist the Working Group; is that right?

A. That's correct.

Q. And were you a voting member?

A. No.

Q. Why were you an invited specialist and not just

10:56:51 part of the Working Group?

A. The invited specialists are people who have needed skills and information but potentially have a conflict of interest. At this time I was working for the Environmental Defense Fund, which is a nongovernment

10:57:08 agency that certainly is vocal about environmental issues

and how they affect people, and they felt that was a potential conflict of interest. And so rather than being a Working Group member, I was an invited specialist.

Q. So to be clear, all the members of the Working Group who actually vote and write the Monograph, they're specifically screened for potential conflicts of interest?

A. That is correct.

Q. And does the IARC Monograph disclose any potential conflicts of interest by all of the people who participate?

A. Yes.

Q. Why do they do that?

A. Transparency. So that people understand who's reviewing the information and what potential biases they might have.

Q. Are all the proceedings and all of the final documents and science that IARC relies upon open to the public?

A. Every piece of science that goes into the IARC Monograph review has to be publicly available.

Q. Now I understand that there's other participants. There's representatives of national and international health agencies; is that right?

A. That's correct. Usually somebody from the EPA,

somebody from NIH might be there, somebody from the European Union, et cetera.

Q. And do they vote?

A. No.

10:58:25 Q. Now can members of the Working Group who do vote, can they be part of some of those agencies?

A. Oh, yes. It could vary the detailed knowledge needed to do the review.

Q. And are there observers who participate as well?

10:58:42 A. Yes, there are observers.

Q. And who are observers?

A. These are people who have an interest in the review that are not national authorities. Usually it's representatives from corporations for the exposures that

10:58:57 are being looked at. Sometimes it's others depending on what the thing is. If you're looking at viruses, you might have CDC there to see what happens, et cetera.

Q. And I understand there's also the IARC secretary; is that right?

10:59:11 A. That's correct. That's members -- that's people who work for WHO.

Q. Are they scientists?

A. Some of them are scientists. In fact, I guess virtually all of them are scientists. Of course, there's

10:59:24 a secretary and an editor and all of that, but

predominantly they're scientists.

Q. And do they vote?

A. No.

Q. So IARC, there was a meeting -- actually, can you please turn to Exhibit 295 in your binder. And this document, what is it, sir?

A. This is the list of participants at the Working Group -- at the Working Group meeting for glyphosate and the other four compounds.

Q. Okay, great. Is this a fair and accurate copy of that list?

A. I guess so. It's a lot of people.

Q. Sure. And to the best of your knowledge, this document was created officially as part of the IARC Monograph program; correct?

A. Yes, it appears in the -- in the technical document, in the Monograph.

Q. And this is typically done in preparing a Monograph for any particular Working Group?

A. Yes.

MR. WISNER: Your Honor, permission to move Exhibit 295 into evidence.

THE COURT: Any objection?

MR. GRIFFIS: No objection, your Honor.

THE COURT: 295 may be admitted.

(Exhibit 295 admitted into evidence.)

MR. WISNER: Permission to publish, your Honor.

THE COURT: Yes.

Q. BY MR. WISNER: We're looking here at the list of participants. I want to go through these quickly. These are the members; right? These are the ones who voted?

A. Correct.

Q. And it looks like Aaron Blair was the overall chair; is that right?

A. That is correct.

Q. And who is Dr. Blair or Aaron Blair?

A. He used to be in charge of cancer epidemiology at the National Cancer Institute before he retired. Now he's an honorary member of the cancer epidemiology group at NCI, world renowned epidemiologist.

Q. Does it have any significance that the overall chair of the Monograph is an epidemiologist as opposed to a toxicologist?

A. No. They've had all kinds of different people chair the IARC Monograph meeting. I have.

Q. That was my next question: Have you ever chaired the IARC Monograph meeting?

A. Yes, I think two. I'm not sure. At least one that I can recall.

Q. How many have you actually been a Working Group member at?

A. I think eight.

Q. All right. Go down on here, we see some other people. We kind of mentioned this earlier. We have, for example, Peter Egeghy, but he looks like he was unable to attend.

Do you see that?

A. Yes.

Q. He was from the Environmental Protection Agency?

A. Yes.

Q. If we go down, we have Matthew Martin. He's also from the Environmental Protection Agency.

Do you see that?

A. Correct.

Q. So he actually participated in the Working Group?

A. Correct.

Q. And voted?

A. Yes. Correct.

Q. We also have down here at the bottom Lauren Zeise of the California Environmental Protection Agency.

Do you see that?

A. That is correct. Yes, I see that.

Q. I assume while you were there, you interacted

with these individuals?

A. Yes.

Q. And discussed scientific issues with them?

A. Many of them I already knew, but yes.

11:02:41 Q. And Dr. Zeise, she's the current head of the Office of Environmental Health Human Assessment here in California; is that correct?

A. OEHHA, yes. Whatever it is, OEHHA, yes. That's my understanding of her current position.

11:02:56 Q. Okay. We also have -- we have some other people on here, but I'll quickly call them out. Matthew Ross, do you see that, Doctor?

A. Yes.

Q. He was specifically in the mechanistic Working

11:03:12 Group; is that right?

A. That's correct.

Q. Now, please clarify to the jury, what are the different Working Groups within the IARC program?

A. So when you -- when you review the literature

11:03:20 for cancer, you -- IARC has broken in most -- most groups that review this literature break it into these four categories. The first category is exposure: How much are humans actually exposed to this particular thing, how much of this particular thing is produced every year,

11:03:40 what kind of information is there out there.

Most of this is not peer-reviewed data. Most of this is government data. So it's just a reiteration of what's out there.

The epidemiology group focuses on human studies, and so that's the second subgroup.

The third subgroup is the animal carcinogenicity subgroup, and they focus on studies in animals specifically aimed at looking at cancer in those animals.

And then there's the mechanism work group, which looks at scientific literature that talks about why this cancer is occurring for this chemical in this population.

Q. And so Dr. Ross, I understand he worked in the sort of mechanistic side; is that right?

A. That's correct.

Q. Okay. And when you were there -- and here's you, Dr. Portier, as an invited specialist. Was there any other invited specialists?

A. No.

Q. And if we see right here, we actually have footnotes disclosing people's various conflicts of interest.

Do you see that, Doctor?

A. Correct.

Q. For you it says you receive a part-time salary from the Environmental Defense Fund, a United States

based nonprofit environmental advocacy group.

Do you see that?

A. Yes.

Q. It also says Peter Egeghy received in kind support and reimbursement of travel expenses and discusses him getting I guess something from the American Chemistry Council.

Do you see that?

A. Yes.

Q. And it looks like that's a nonprofit scientific research organization based in Washington DC and funded by corporate sponsors.

Do you see that?

A. No, the Chemistry Council is an industry trade association. The Health and Environmental Sciences Institute, HESI, is a nonprofit scientific research group.

Q. I'm sorry. So the American Chemistry Council, that's an industry trade group?

A. That's an industry trade group.

Q. And I know -- this is Dr. Egeghy, he's from the EPA. But he did not actually attend. So it was sort of a non-issue.

A. Correct, but everything is transparent. So they put that there anyway because they did invite him and he

would have been able to vote.

Q. Okay. And just to be clear: You weren't allowed to be in a Working Group because you had a conflict of interest working for the Environmental
11:05:58 Defense Fund, but Dr. Egeghy would have been able to vote even though he had gotten money from an industry trade group?

A. Well, his money was reimbursement of travel funds. It wasn't money that they were paying to him
11:06:11 personally. So I think that was the distinction they would have made in this case.

They -- I was included -- remember I talked about the National Toxicology Program and changing the way in which toxicology is done? Well, this was the
11:06:29 first Monograph where that effort was actually providing data to be interpreted by IARC. So there was a big mass of data on the other pesticides. Nothing on glyphosate. But because I had started that program, because I had worked very hard with making it happen and analyzing it,
11:06:50 I was included for that specific reason, to help them with that problem.

Matt Ross -- I mean Matt Martin from EPA, that's what he does. He evaluates that type of data. So that's why he's in the mechanism group.

11:07:06 Q. I got you.

So you actually weren't invited to participate in the Monograph program because of glyphosate, but the other pesticides that were really at issue?

A. Correct. The mechanistic data that was available on those other pesticides coming out of what's called the Tox 21 program, toxicology for the 21st century.

Q. All right. Then we also have representatives of national, international health agencies.

Do you see that?

A. Yes.

Q. It looks like we have someone from the EPA, the French agency for food environmental and occupational health and safety. It looks like those are the only two people who attended.

A. Correct.

Q. And then we have observers, and there's a bunch of people listed here.

Do you see that?

A. Yes, I do.

Q. And there's one for Cheminova.

Do you see that, Doctor?

A. Yes.

Q. One for European Crop Protection Association.

Do you see that?

A. Yes.

Q. And who are they?

A. Cheminova is a chemical manufacturer, and they make glyphosate and other pesticides. I don't know if they make the other pesticides there.

The European Crop Protection Association is an industry trade group in Europe looking at pesticides. They call them crop protection products or plant protection products, but they're pesticides. And they advocate in terms of that issue.

Q. And obviously we have someone here from Monsanto.

Do you see that?

A. Yes.

Q. And it looks like down here it even discloses who these different people are. For example, for Cheminova it says it's a global company developing and producing and marketing crop protection products.

Do you see that?

A. Yes.

Q. And when we say "crop protection," I just want to be clear. We're talking about pesticides, herbicides, and glyphosate?

A. Yes. I don't know if it includes -- I don't think it includes chemicals that are put into the ground

to help them grow, fertilizers, but I think pretty much everything else.

Q. All right. So these participants all went to this Monograph, and I understand there was an ultimate vote at the end about all the different sections of the Monograph, its contents, and the conclusions; is that right?

A. Correct.

Q. And that's a systematic voting on every section of the Monograph; is that right?

A. Yeah, there's a -- there's a whole process by which you evaluate the literature. You look at each individual study by itself first to make sure the study is well done, high quality, what they've concluded makes sense. So you review each study for that.

Then once you have a group of studies -- let's take one group. Animal data. Animal cancer studies. So I've got like say five studies done in animals looking to see if the animals get cancer or not. Then I take all five of those studies and now I review them together looking at whether as a whole do they tell me that cancer can be caused in animals by exposure to glyphosate.

And IARC has categories for that. They have inadequate. So I can't tell. There's problems with these studies. There's not enough information. They

conflict. I can't reach a decision. That's inadequate.

Then they have what's called sufficient evidence, and that's where I'm absolutely certain this chemical caused cancer in these animals. I'm absolutely certain of it.

11:10:47

And then you have this category in between called limited evidence, and that's a case where you don't have enough evidence to say sufficient but it's not inadequate. It's in between.

11:11:00

So sufficient evidence, I might consider sufficient evidence to be not only just one study of animal -- in one animal of cancer, but I have to have it replicated. I need at least two. That would be sufficient, in which case then one study would be limited

11:11:17

evidence, if it was positive.

So that's how they break that down.

Then -- and they do that in each category. So epidemiology has inadequate, limited, and sufficient. Sufficient in epidemiology means we really believe that

11:11:34

for this chemical this epidemiology data is so clear that this chemical causes cancer in humans.

At that point you don't actually need anything else. At that point you've already made a decision that it causes cancer in humans. So sufficient in

11:11:50

epidemiology is a very strong finding.

The in-between category, limited, is when there's data, it's suggested, but you worry about some aspects of the data. It's not as strong as sufficient, and so it falls in this limited category.

11:12:08 And then there's the mechanistic data, and that's either strong, medium, or weak, I think is the categories they use.

Now you've done each of the three areas. Now you have to pull them together into a final decision.

11:12:22 And IARC has a starting point for you for that. For example, if it's limited evidence in humans and sufficient evidence in rodents, then you're starting at what they call Category 2A, probable human carcinogen.

And so that's where you start your discussion,

11:12:41 and then the whole group sits down and discusses this and says, well, it might be 2A, but we think the mechanism is so strong we're going to make it sufficient, known human carcinogen. We're going to put it in Category 1.

Or they might say, yeah, we have sufficient

11:12:59 evidence in animals and limited evidence in humans, but the human evidence is so weak and there wasn't really that much animal evidence, we're going to put it in 2B, which is possible human carcinogen.

So they can twist it around depending upon how

11:13:16 much information they feel is there. But they have

starting points.

Q. And so it would be fair to say they kind of weigh all the evidence and look at everything and kind of come to a conclusion?

11:13:25 A. Correct.

Q. I want to clarify one thing. You talked about in epidemiology there's a category called limited evidence; right? I actually want to show you on Exhibit 166, page 19, Doctor. I'm going to put it up.

11:13:43 It actually defines here carcinogenicity in humans, and it says "limited evidence of carcinogenicity."

Do you see that --

A. Yes.

11:13:51 Q. -- at the bottom? I'm going to go to the next page in a second. But it says: "A positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance bias or

11:14:07 confounding cannot be ruled out with reasonable confidence."

Do you see that?

A. Yes, that is correct.

Q. So when you find a limited classification for

11:14:17 epidemiology, there is a credible causal association

observed. You just can't confidently rule out chance bias or confounding; is that right?

A. That is correct.

Q. Let's talk about those. What is chance?

11:14:33 A. Chance is I did a study and because the response is somewhat tied to probabilities like flipping a coin or tossing dice, there's some probabilities associated with it.

So, for example, in unexposed people, the 11:14:54 probability of getting this cancer might be one in 100,000, and exposed, it's five in a 100,000.

Well, there's a chance, a probability, that that just occurred because of chance. I got the wrong five people in my hundred thousand, for example. I just 11:15:13 simply -- it's chance. And so that's a possibility.

Bias is when you -- when you choose how to design these studies, you do things like ask questions of people, and sometimes the people can be biased in their response because they know something that -- that is 11:15:34 biasing them towards that response.

In addition, you can do things in the analysis of the study that can create bias that you want to look at as well.

Confounding is when you have something that is 11:15:49 closely related to the chemical you're interested in and

it could cause the same disease. Then if you don't concern yourself with that in the analysis, and it's a potential confounder, and if it hasn't been included in the analysis, even though you see a positive result, it could be due to the other thing. And so that's what a confounder is, and sometimes you can't rule that out.

Q. And to be clear, a confounder there's two aspects to it; right?

A. Correct.

Q. The first aspect is that it can cause disease; right?

A. Correct.

Q. And the second aspect is that it's differentially associated with the exposure?

A. That's correct. People who have the exposure are also likely to have the other exposure or the other way around. It depends how the risks go.

Q. But if you're studying a population and both the exposed and unexposed group are equally exposed to that potential confounder, does confounding occur?

A. You only know that if you actually evaluate it. So you would actually have to check and see if it was a real confounder in that study. It's the potential confounder you want to check for it.

Q. And Doctor, are there ways to examine chance,

bias, and confounding?

A. Yes, of course.

THE COURT: Mr. Wisner.

MR. WISNER: Yes.

11:17:17 THE COURT: I think this might be a good time to take our morning recess.

Ladies and Gentlemen, let's take a brief morning recess. We'll resume again at 11:30 on the wall clock. All right? And please remember: Do not discuss the

11:17:30 case. Thank you.

(Recess.)

THE COURT: Welcome back, Ladies and Gentlemen.

Dr. Portier remains under oath, and Mr. Wisner may resume.

11:31:02 MR. WISNER: Thank you, your Honor. Before we proceed, I'd like to officially move to have Dr. Portier recognized as an expert in the field of cancer risk assessment.

THE COURT: Any *voir dire*?

11:31:16 MR. GRIFFIS: Not at this time, your Honor.

THE COURT: All right. Then I will accept Dr. Portier as an expert in the field of cancer risk assessment.

Q. BY MR. WISNER: Is that the right one, Doctor?

11:31:28 A. That's fine.

Q. Okay. Let's continue on with your --

MR. WISNER: Oh, sorry, your Honor. May I proceed?

THE COURT: Yes.

11:31:36 MR. WISNER: Okay. I realize I didn't ask for that.

Q. Okay. All right. Doctor, I don't want to spend too much time on the Monograph, but I do want to talk about it quickly. Let's look at Exhibit 784. It should

11:31:50 be in your second binder.

A. Okay. I have it.

Q. What is this document, sir?

A. This is the part of the Monograph that deals with glyphosate.

11:32:07 Q. And when you say "the part of the Monograph," what does that mean?

A. The Monograph looked at five different pesticides. This is one of them, so this is the part of the Monograph that focused entirely on glyphosate.

11:32:21 Q. And this document was created by the IARC Working Group; is that right?

A. That is correct.

Q. And you were part -- you participated in the scientific discussions that predated this Monograph? Let

11:32:37 me ask a better question.

You participated in the scientific discussions that led to the creation of this Monograph?

A. Yes.

Q. And you've reviewed this document?

11:32:48 A. Some parts of it while we were looking at it, but again, I was not allowed to write, so in reviewing it, of course I read it, but I couldn't give feedback to say -- that I'd say, "I think this sentence should be this one," but we could discuss the science.

11:33:05 Q. Fair enough. That was a poorly worded question.

Have you read the document and relied upon it in your assessment of the cancer risk for glyphosate in Roundup?

A. Yes.

11:33:15 Q. Okay. And this document was created as part of the official Monograph program in the regular course of IARC's business; is that right?

A. Correct.

MR. WISNER: At this time, your Honor, I would

11:33:26 move Exhibit 784 into evidence.

MR. GRIFFIS: No objection.

THE COURT: All right. Exhibit 784 may be admitted.

(Exhibit 784 admitted into evidence.)

11:33:34 Q. BY MR. WISNER: Doctor, this document is, I

think, 92 pages, and I don't want to read it all, but I just want to go through quickly some of the sections. Okay?

A. Yes.

11:33:42 Q. We have up here glyphosate, and you see the section that reads: "Exposure Data"?

A. Yes.

Q. And so the first section actually looks at the exposure -- well, let me ask you: What does the first

11:33:52 section look at?

A. Exposure in the human populations, how much is produced and sold worldwide, if the evidence is there, and then if there are very specific exposure variables created in epidemiology studies, they also review that.

11:34:09 I don't know if it's in this section or in the epidemiology section, but this group focuses on that as well.

Q. And would it be a fair criticism of IARC to say that they don't look at exposures that are occurring in

11:34:22 the real world?

A. Well, of course they do. That's what this chapter is on, and in -- all of the human epidemiology studies are based upon human exposures, which means they're in the real world.

11:34:36 Q. Are you familiar with this distinguish between a

risk assessment and a hazard assessment?

A. There are many different subtle definition interpretations around the world on those two things, but, yes, I'm -- I'm aware of what they are.

11:34:52 Q. And are you aware of what IARC does with regards to determining a risk of cancer?

A. Well, they determine whether there's a potential risk of cancer from that data that they're looking at, but they don't actually determine the risk.

11:35:08 Q. And so to look at whether -- so would it be fair to say, then, that IARC determined if it can cause cancer, but if it causes a specific person's cancer, you have to look at that specific person?

A. Yeah, they would never even go near that

11:35:23 question.

Q. Okay. So we're just looking at the higher level question of can this substance cause cancer?

A. Correct.

Q. All right. And the first section is exposure,

11:35:31 and then if you flip through some of these pages, it goes on for several pages, and then we have here -- well, I'll turn this over. This is a -- Table 1.2.

Do you see that, Doctor?

A. Yes.

11:35:42 Q. And this table goes on for a bit, and then it

talks about air exposure, water exposure, household exposure, biological marker.

Do you see that?

A. Yes.

11:35:54 Q. It goes on for a bit, and then there's this thing right here. I just want to ask you a quick question about this, because it might come up if someone reviews this document. What is -- it says right here, "Table of concentration of glyphosate in AMPA."

11:36:09 What is AMPA?

A. AMPA is, I would say, metabolite. It is a decay product of glyphosate, so when glyphosate is in the environment, it's one molecule. The sun, other things in the environment, can break it down into a new molecule.

11:36:28 AMPA is one of those new molecules.

Q. And as part of the Monograph program, did -- did the Working Group look not just at glyphosate but also the effects of AMPA on human health?

A. Correct. We looked at all kinds of information

11:36:42 on AMPA.

Q. All right. If we keep going, there's a lot of tables. Now, we get into the second section, "Cancer in Humans."

Do you see that, Doctor?

11:36:51 A. Yes.

Q. And is this section specifically about epidemiological studies?

A. Yes.

Q. It says right here cohort studies.

Do you see that?

A. Yes.

Q. What types of epidemiological studies are there?

A. For the purposes of this discussion, cohort studies and case control studies.

11:37:05 Q. What's the difference?

A. In a cohort study, you take a very large number of people and you ask them questions about their exposure, and then you follow them, and every few years, you ask them questions about their exposure, and you 11:37:22 determine if any of them have gotten cancer or not. And after you go long enough, you've collected enough cancer cases that maybe you can look at whether cancer cases in people who are not exposed are equal to or less than cancer cases in people who are exposed, and you can see 11:37:42 if there's a difference.

Case control studies are quite different. In a case control study, you take a bunch of people that have cancers and a bunch of people who look like them but don't have cancers, and then you ask them about their 11:37:57 exposures and see if the people with cancer have more

exposure to the thing you're interested in than the people without cancer.

Q. Now, individuals -- is cancer generally considered a rare disease?

11:38:12 A. Yes.

Q. And so to study cancer in humans, you need to look at a lot of people; is that fair?

A. It's one of -- one of the reasons you do case control studies for rare diseases, and cancer being one

11:38:27 of them, is because you don't have to try to find a population of 200,000 people. You're drawing from the general population, which is huge, and you're only selecting the cancer cases. If you want to do a cohort study for cancer at any point, it has to be a very large

11:38:44 population and a very long time.

Q. And in case control studies where they identify people who are suffering from non-Hodgkin's lymphoma, what sizes of populations do they have to draw from?

A. Well, it depends on the study. Some of the

11:39:01 studies in Sweden, I believe, were a substantial portion of the Swiss population, because they looked at all NHL cases for a certain period of time in a certain section of Sweden.

In one of the US-pooled studies, they looked at

11:39:21 three states, every male in -- of certain age in two of

the states, and then in one of the other states, just parts of it, about 2 million population, I would guess, so that's where they're drawing from.

Q. Would it be possible to do a cohort study with 2 million people?

11:39:38

A. It's never been done, that I'm aware of. People have attempted to. There are pooled cohort studies, so, for example, the United States had a children's health study, so does France, so does England, so do others. So those people get together, work out to make sure they do the same kind of study, and then in the end, they pool the data. So you can get near a million people in some of these pooled studies.

11:40:02

Q. In the agricultural occupational health field, has there ever been a cohort of a million people?

11:40:18

A. Not that I'm aware of.

Q. All right. So then moving through this, as we see here, there's a table discussing the cohort studies of cancer and exposure to glyphosate.

11:40:34

Do you see that, Doctor?

A. Yes.

Q. And then, obviously, there's actually one study here; is that right?

A. That's correct.

11:40:41

Q. And that's the American Agricultural Health

Study -- I'm sorry -- the Agricultural Health Study; is that right?

A. That's right.

Q. We're going to talk about that later. I just wanted to flag that.

11:40:49

And then moving on, this is discussing all the studies, and then this is a case-controlled study on non-Hodgkin's lymphoma, multiple myeloma and leukemia.

Do you see that?

11:41:05

A. Yes.

Q. One of the things I wanted to clarify: Was the Working Group at IARC just looking at non-Hodgkin's lymphoma or all forms of cancer?

A. They looked at all epidemiological data where

11:41:16

glyphosate was identified as a potential cause, so anything in epidemiology. So there were studies on non-Hodgkin's lymphoma, studies on multiple myeloma and studies on leukemia, and so those were the things they looked at.

11:41:31

Q. All right. So turning to this document, there is several tables. It goes on for quite a while. This is all looking at the various case control studies for glyphosate; is that right, Doctor?

A. Correct.

11:41:44

Q. And then it goes on to describe in narrative

format all these documents.

Do you see that, Doctor?

A. Yes.

Q. So, for example, here there's cross Canada case control study, McDuffie, et al., 2001.

A. Yes.

Q. And it goes on to describe the results and the strengths and weaknesses of the study; is that right?

A. That's right.

Q. And like, for example, there's these comments, and I just want to, sort of, get your sense of this. Like, for example, here it said the study has -- do you see it's in brackets? "The study had relatively low response rates. Multiple myeloma is not considered a subtype of NHL."

Do you see that?

A. Yes.

Q. What do those brackets mean?

A. The brackets are there to put in -- specifically, these are comments from the Working Group. The rest is supposedly statement of fact about the science, and then this tells you something about what the Working Group thought of this specific study.

Q. And the Working Group goes through each study and decides if they're going to use it or not use it; is

that fair?

A. That's fair.

Q. And so it keeps going on. We have this epi section for longer. We have this section not about NHL, but other types of cancer. Do you see that? Esophagus and stomach?

11:42:56

A. Yes. Uh-huh.

Q. All right. Keep going. And then we get to Section 3, "Cancer in Experimental Animals."

Do you see that?

11:43:07

A. Yes.

Q. And that refers to what?

A. Two-year or chronic exposure, animal carcinogenetic studies.

Q. And those are primarily in mice and rats; is that fair?

11:43:15

A. They're -- in this particular case, they're entirely mice and rats, and they're usually mice and rats.

Q. Okay. So it goes on to discuss the toxicology data for a bit. It separates it by mice and rats, and now we have the rat section.

11:43:23

Do you see right here, Doctor?

A. Yes.

Q. You then we keep going. There's tables about

11:43:33

everything, review articles. Okay. Great.

The fourth section is "Mechanistic and Other Relevant Data."

Do you see that, Doctor?

11:43:42 A. Yes.

Q. And it says, "Test toxic kinetic data." What is that?

A. When you -- when you ingest a chemical, so you absorb it, it gets distributed through your body. It

11:43:55 gets turned into other chemicals by proteins in your body and enzymes, so it gets metabolized, and then you eliminate it, urine, feces, through breathing. And so toxical kinetic data deals with that issue, absorption, distribution, metabolism and elimination.

11:44:12 Q. When we talk about mechanistic, are we talking about the mechanisms by which a substance could cause cancer?

A. Correct.

Q. Okay. And this goes on for a bit, and they have

11:44:21 all these different sections on it, and at some point -- I'll just show this table. This is a table -- so it says, "Genetic and related effect of glyphosate in exposed humans."

Do you see that, Doctor?

11:44:38 A. Yes.

Q. And what is that referring to?

A. Experimental studies that look at genetic endpoints, things that look for whether glyphosate is damaging the gene or in some other way interacting closely with the gene.

Q. Is that reflected, for example, here where it says, "DNA damage"?

A. Yes.

Q. Okay. Great.

And then this table, it looks like it says the tissue that was studied, the cell type, the endpoint, the test, the description of the exposure and controls, and it goes on and on.

Do you see that, Doctor?

A. Yes.

Q. All right. And so this tables goes on for -- that's one table, and then there's another table here, "Genetic and related effects of glyphosate AMPA in glyphosate-based formulations in human cells and *in vitro*."

Do you see that?

A. Correct.

Q. This is actually a question that came up, is the IARC Monograph just looking at glyphosate, glyphosate formulations or this AMPA?

A. It looked at all three.

Q. Okay. So the classification ultimately entered by IARC effectively relates to all three?

A. Correct. They have statements on all three.

11:45:49 Q. Okay. And then this table goes on for a bit, and then there's another table. This is genetic and related effects of glyphosate, AMPA and glyphosate-based formulations on non-human mammals *in vivo*."

Do you see that?

11:46:05 A. Correct.

Q. What does that -- what does non-human mammals *in vivo* mean?

A. Well, the first table was in humans, and that's *in vivo* in humans. The second table was *in vitro* in

11:46:16 humans, that is taking human cells and looking at the cells in a petri dish in a laboratory. This one is taking animals and exposing them to these compounds and looking for DNA damage, looking for gene effects.

Q. And these are classifications of tests that are

11:46:34 pretty standard in the area of cancer evaluation?

A. In terms of classification?

Q. This way of looking at different tests in different categories of mammals, non-mammals, *in vitro*, *in vivo*, that's standard procedure?

11:46:45 A. Very standard. Yeah. You look in -- basically,

you break it up into six boxes. Two of the breakdowns is in the animals or in the cells of the animals, and then the other three breakdowns are humans, mammals -- then not humans, but mammals, and then everything else.

11:47:06 Q. And everything else, that includes everything from fish to single-cell organisms; is that right?

A. Yeah. They -- this has a very broad range of everything else.

Q. So the Monograph goes on -- this table goes on

11:47:21 for quite a ways, and each one of these entries is referring to a study that the IARC Working Group reviews; is that right?

A. That is correct.

Q. And so it's going. And then they review all

11:47:34 this data, and they ultimately decide to bring it all together into an official characterization; is that right?

A. That's correct.

Q. All right. So I'm not going to go through the

11:47:44 summary. I'm just going to go to the conclusions section. And we have here the evaluation. This is the final section of the report.

Do you see that, Doctor?

A. Yes.

11:47:53 Q. All right. It says, "Cancer in humans. There

is limited evidence in humans for the carcinogenicity of glyphosate."

What does that mean?

A. As we discussed before, limited evidence means there is an association. Causal linkage is reasonable, but you can't rule out chance, bias or confounding.

Q. So would it be fair to characterize that as more likely than not?

MR. GRIFFIS: Your Honor, I need to approach on this, please.

THE COURT: Yes, you may approach.

(Discussion off the record.)

THE COURT: All right. You may continue, Mr. Wisner.

MR. WISNER: Thank you, your Honor.

Q. So we're talking about this limited classification, and I asked you a question about the likelihood here. Let's move on from that for now. I'll just ask you a separate question.

In your opinion, does the evidence related to epidemiology, as reviewed in the IARC, suggest to you or -- strike that. I'll ask the question later. Let's move on to the next sentence. Let's back up.

It says, "Limited evidence," and we established earlier that that, per IRAC's definition, means a causal

association has been observed. You just can't rule out chance, bias or confounding with confidence; is that right?

A. It means an association has been observed. It's possible that it's causal, but chance, bias and confounding can't be ruled out.

Q. Well, let's actually look at the definition, because I think it's actually stronger than that, Doctor.

A. Okay.

Q. Turn to Exhibit 166, again. I'm sorry. Make sure I get the number. 166.

Are you there, Doctor?

A. In a sec.

Q. Okay.

A. Yes.

Q. All right. Let's go to page 19, very bottom. And actually, you can just look at the screen. I guess that's easier.

"A positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible."

Do you see that?

A. Yes.

Q. Okay. So I guess maybe my question was poorly

asked. I think you were probably more accurate, now that I think about it.

So that limited classification of the epidemiology does, in fact, include a conclusion that a 11:54:11 credible causal -- causal connection has been observed?

A. I've lost it here. It was here a minute ago.

Next -- yeah. Next page. It's -- it's credible. That the association could credibly be causal.

Q. Okay. Great. Now we're on the same page.

11:54:35 All right. So let's go back to the Monograph.

A. Can I define what "causal" means?

Q. Yeah, please.

A. Would you like me to do that? Because we use it a lot, and maybe it's unclear.

11:54:46 Q. Sure.

A. You can see associations which are not actually true. The classic example is the number of storks in Europe over time and the birth rate in Europe over time. They follow each other very closely. But the drop in 11:55:07 storks is not what's causing the drop in births in Europe. So there is an association, but it's clearly not causal.

And so we have to be careful in looking at associations to ask our question: Is it credible that 11:55:21 it's causal, or is it really causal? That makes a big

difference.

Q. Okay. So here IARC is saying there's a credible causal association?

A. Correct. If it wasn't credible that there'd be causal association, this would not be limited.

11:55:33

Q. Okay. It would be in a lower category; is that correct?

A. Correct.

Q. All right. Then it goes on to say, separate from that limited classification, states: "A position association has been observed for non-Hodgkin's lymphoma."

11:55:40

Do you see that?

A. Yes.

Q. What does that mean?

11:55:46

A. Well, it's -- it's -- when you say "limited evidence," that has to be an association there. So they have to declare what it is so the reader understands what they're talking about: This is where they saw the association. If they'd have seen it with two or three other cancers, they'd all be listed here.

11:55:59

Q. So the only ones that IARC actually saw was actually non-Hodgkin's lymphoma?

A. That's correct.

Q. All right. And then we have cancer in

11:56:11

experimental animals. There is sufficient evidence in experimental animals for the carcinogenicity of glyphosate.

Do you see that?

11:56:20 A. Yes.

Q. What does that mean?

A. That it's -- there's an association, and it's causal.

Q. Okay. So there's no hesitation there?

11:56:26 A. No hesitation there. The chemical caused the cancer seen in the animals.

Q. Okay. And then it has this rationale and -- and it reads down, starting in the second paragraph, "In addition to limited evidence for the carcinogenicity of

11:56:41 glyphosate in humans and sufficient evidence for the carcinogenicity of glyphosate in experimental animals, there is strong evidence that glyphosate can operate through two key characteristics of known human carcinogens and that these can be operative in humans."

11:56:57 Do you see that, Doctor?

A. Correct.

Q. And the first one says, "Specifically, there is strong evidence that exposure to glyphosate or glyphosate-based formulations is genotoxic based on

11:57:08 studies in humans, *in vitro* and studies in experimental

animals."

Do you see that doctor?

A. Yes.

Q. What is the highest categorization of mechanistic data that IARC gives?

11:57:17

A. Strong evidence.

Q. So we're just doing a tally here. We have the second highest classification for epi. We have the highest classification for toxicology in animals. And then we have the highest classification for mechanism.

11:57:34

A. For one mechanism, yes.

Q. Okay. And even though we have the second highest, highest, highest, that wasn't enough to actually put it in the highest category for IARC; is that right?

11:57:51

A. That's correct.

Q. It was put into a Class 2A carcinogen; is that right?

A. That's correct.

Q. And that is -- and that is -- specifically, that is a probable human carcinogen?

11:58:03

A. That's correct.

Q. What was the vote?

A. I don't -- I don't recall. I'm just -- I'm sorry, I don't. I read things that said it was unanimous, but I'm not absolutely certain I was paying

11:58:19

attention.

Q. Okay. But it's your understanding --

A. Because I didn't vote. It was not my job.

Q. But it's your understanding that the vote at the IARC Monograph meeting was unanimous?

11:58:30

A. That's my understanding.

Q. And that would have included the director of the California -- OEHHA of EPA for California?

A. Yes, of course.

11:58:40

Q. That would have included that mechanistic scientist from EPA?

A. Yes.

Q. All right, Doctor. Following IARC's classification of glyphosate and glyphosate formulations as a probable human carcinogen, was there a response in the scientific community?

11:58:53

A. Yes. There was a response in virtually every community. It -- there was a lot of discussion.

Q. Were -- I'll be frank: Were you or any of the members of the IARC Working Group attacked by Monsanto or industry groups?

11:59:14

A. You know, I -- I don't know who was behind a lot of different press dealing with reputations and biases and all kinds of things, so I can't claim it's Monsanto or anybody else. But certainly there was a lot of that.

11:59:37

Q. Well, I'm going to show you a document that's in evidence that might help you get to the bottom of that.

Let's look at Exhibit 292. It's already in evidence.

11:59:56 MR. GRIFFIS: We have an objection to this, your Honor.

THE COURT: Is this in evidence?

MR. WISNER: Yes.

MR. GRIFFIS: We have an objection to it being

12:00:04 shown to this witness. It's not on his materials considered list.

THE COURT: All right. Actually, this might be a good time to break for the lunch recess, so we can discuss this.

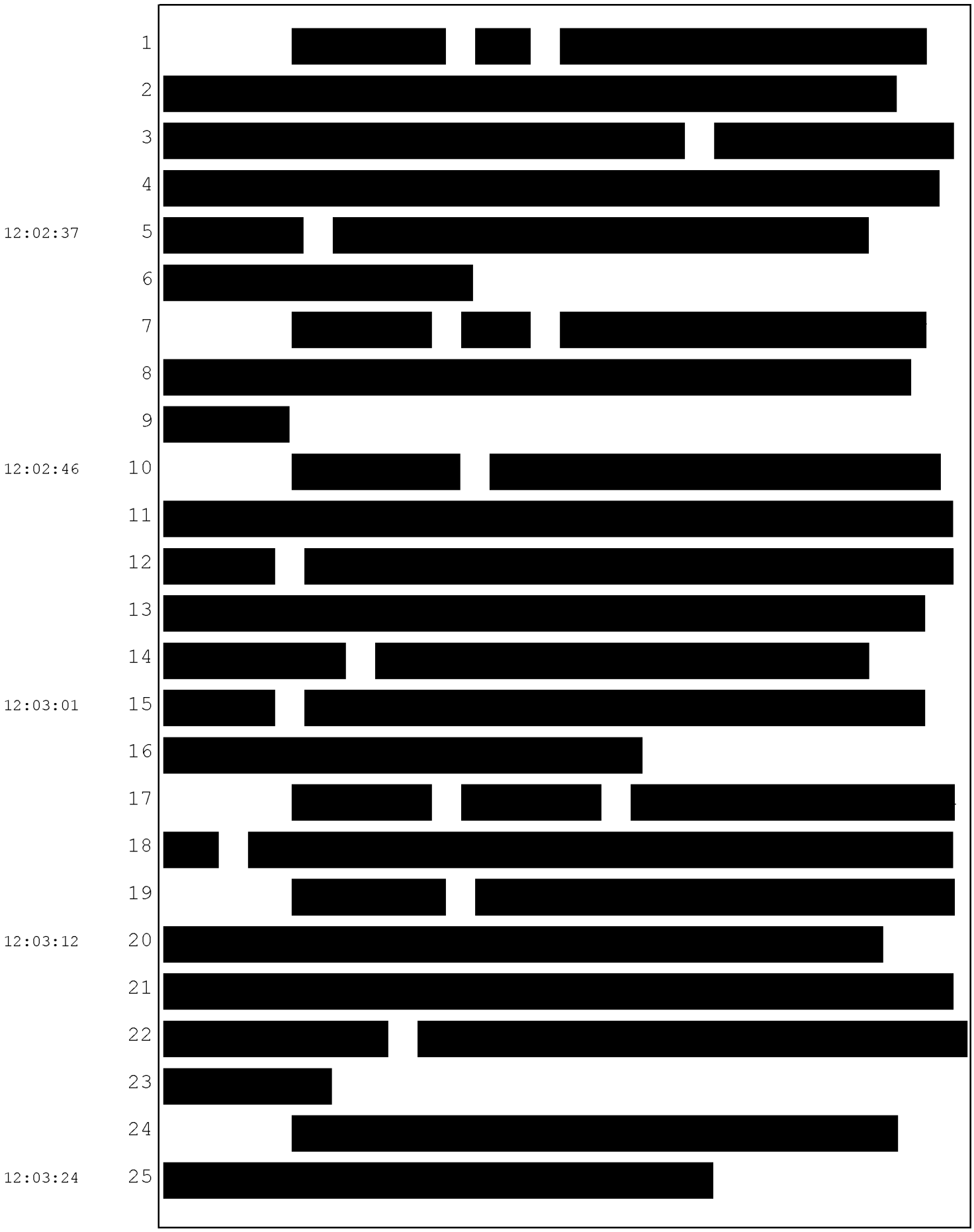
12:00:15 All right, Ladies and Gentlemen. We're going to recess now for the lunch break. Please do not discuss the case with each other, with anyone else. Please don't do any research. And we'll see you back at 1:30.

Counsel, can you please remain?

12:01:42 (Jury leaves courtroom.)

[redacted]

12:02:24 [redacted]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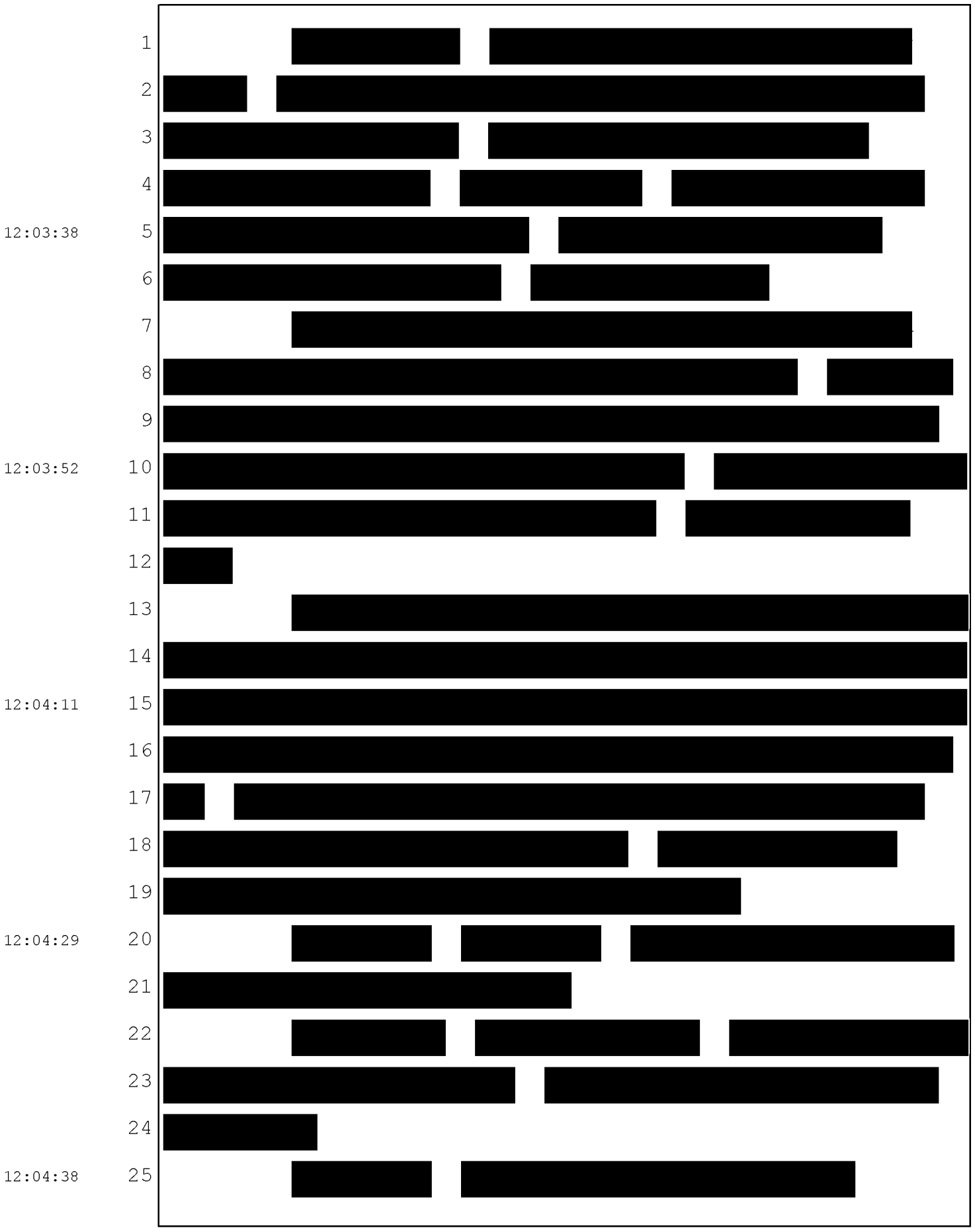
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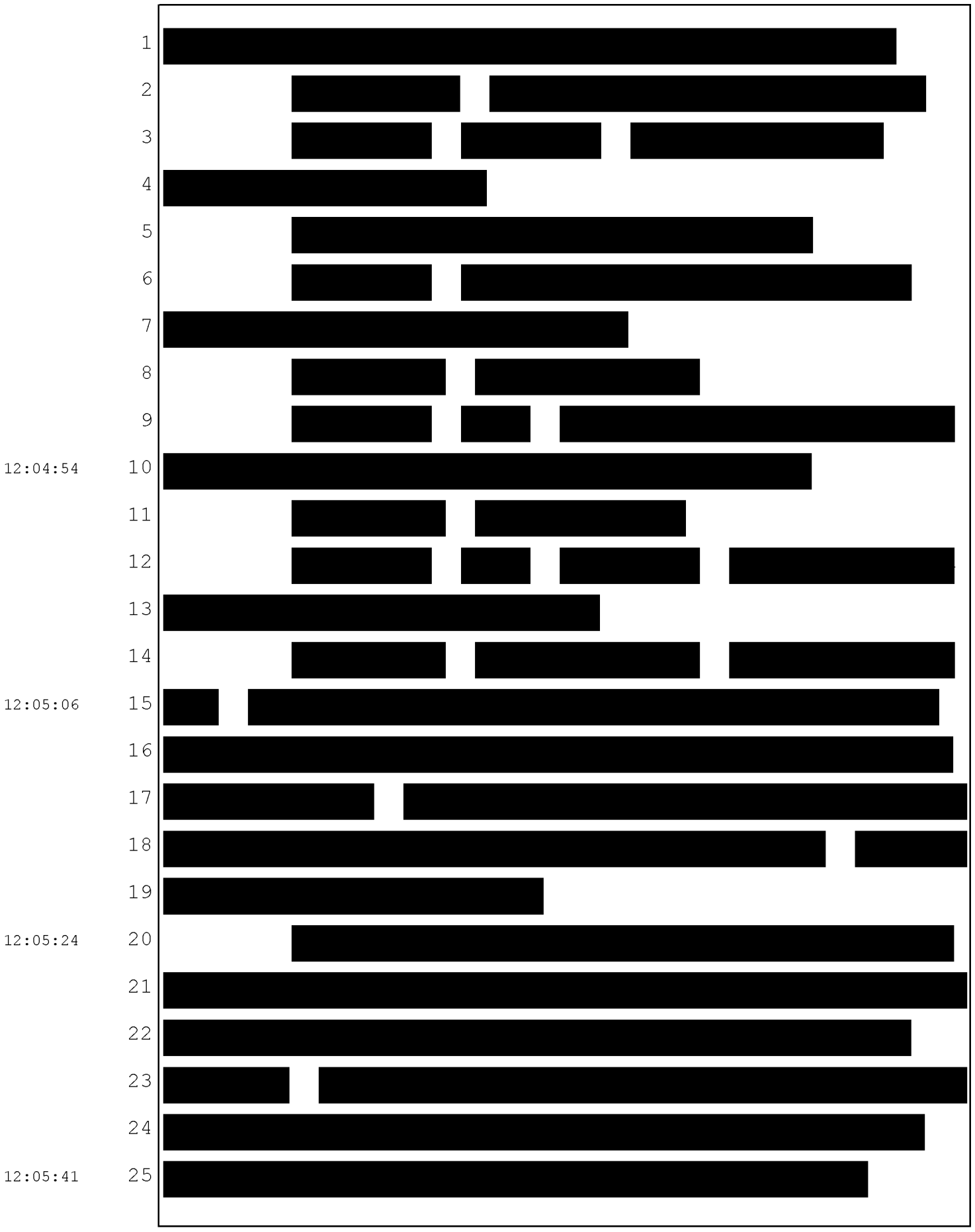
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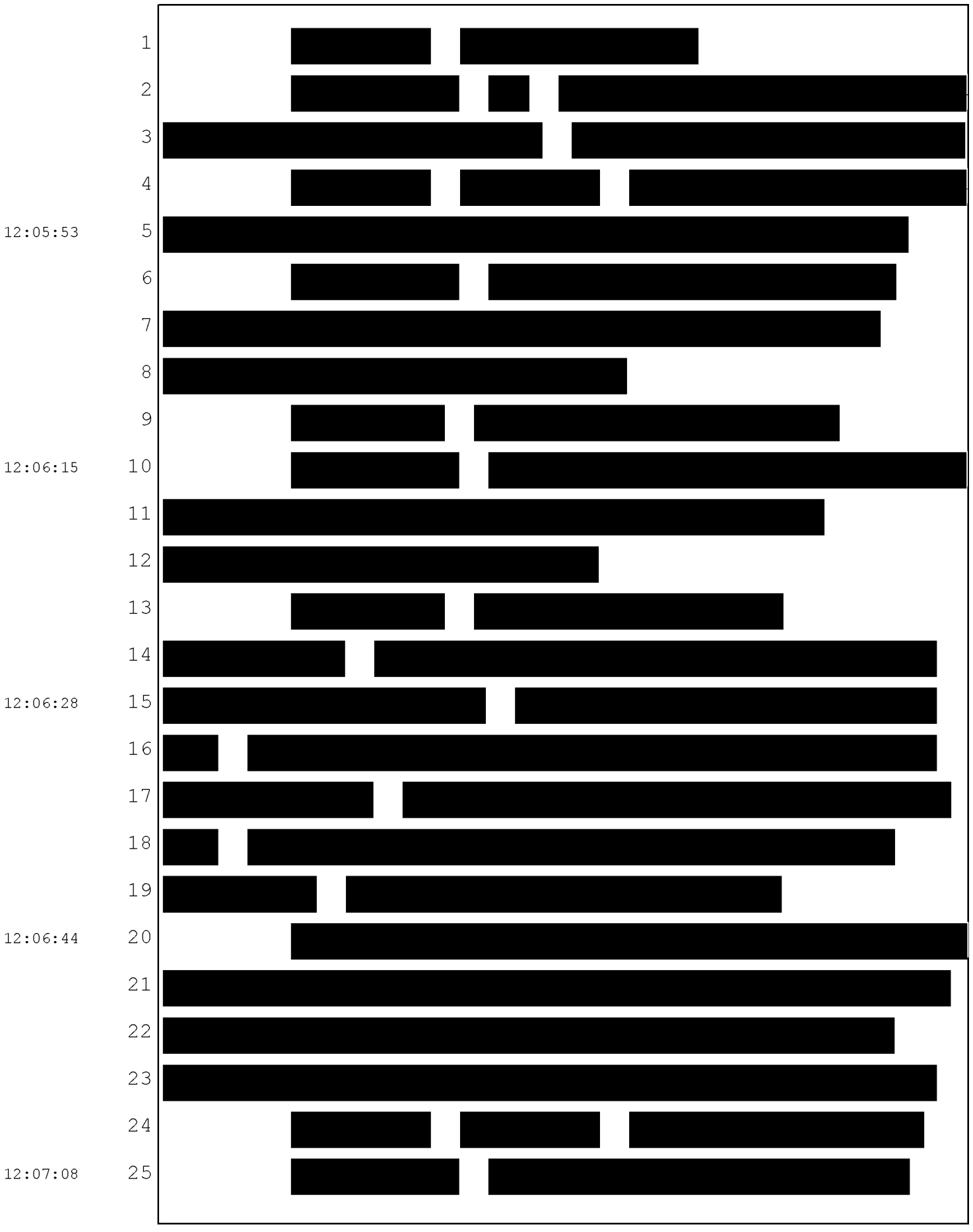
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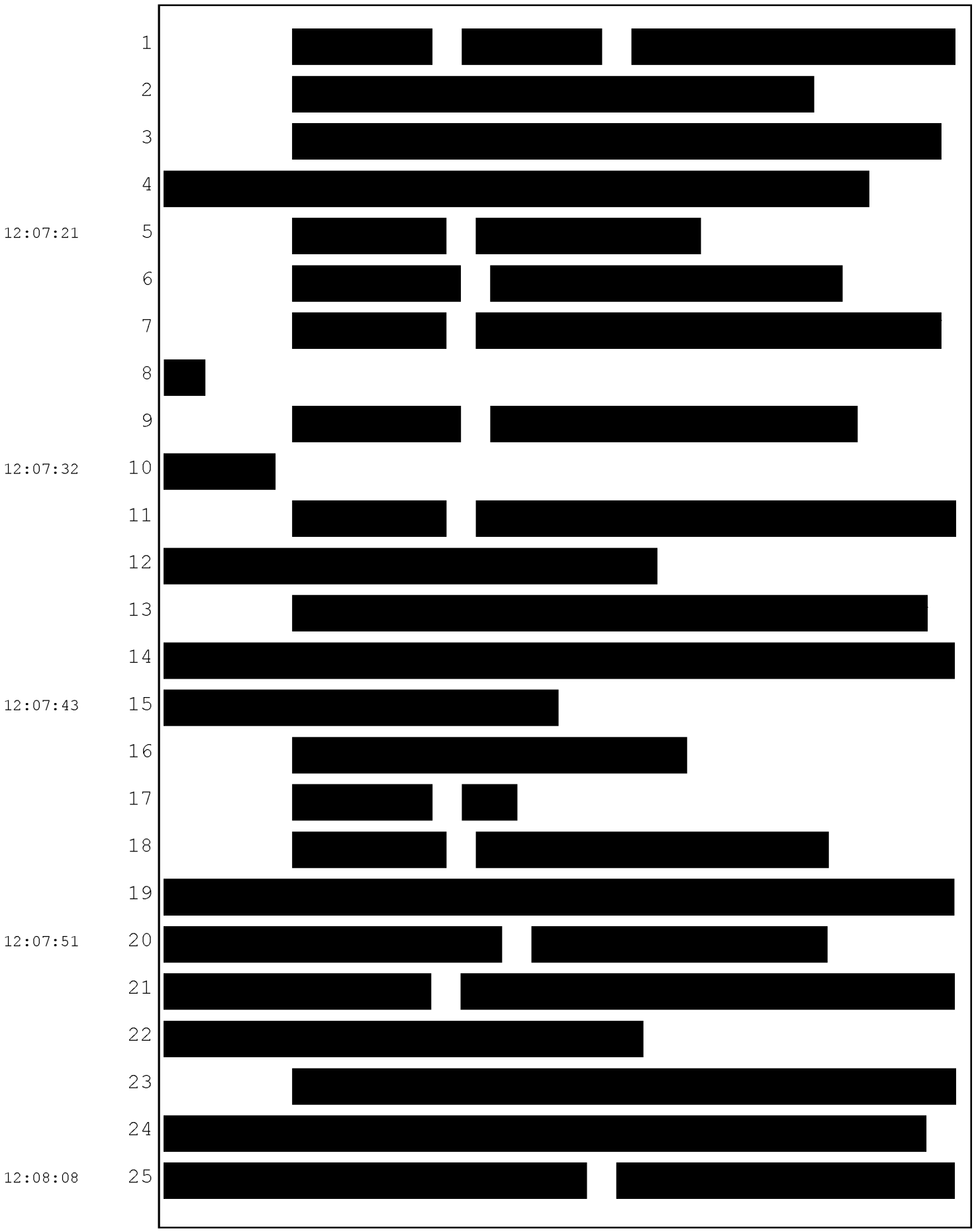
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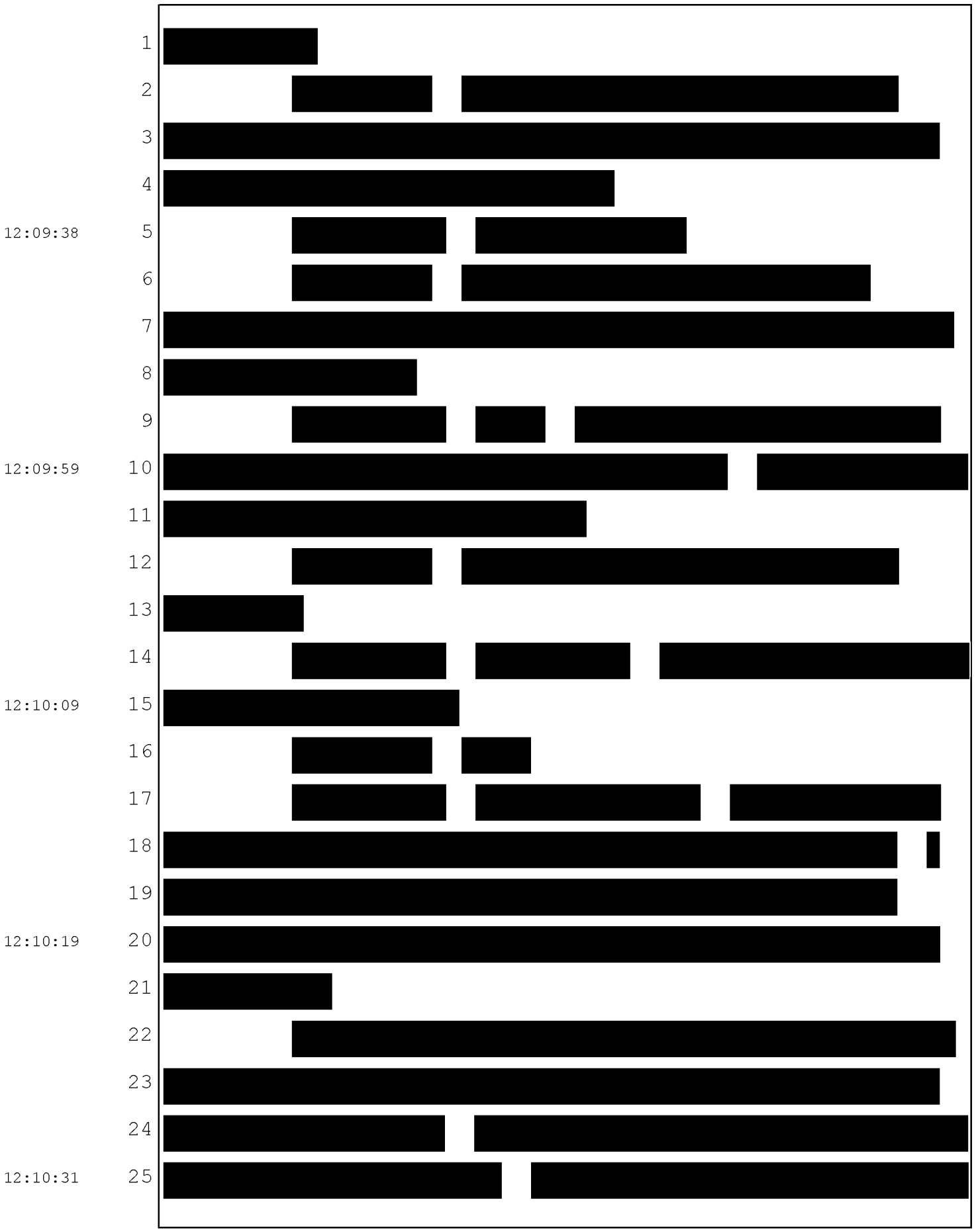
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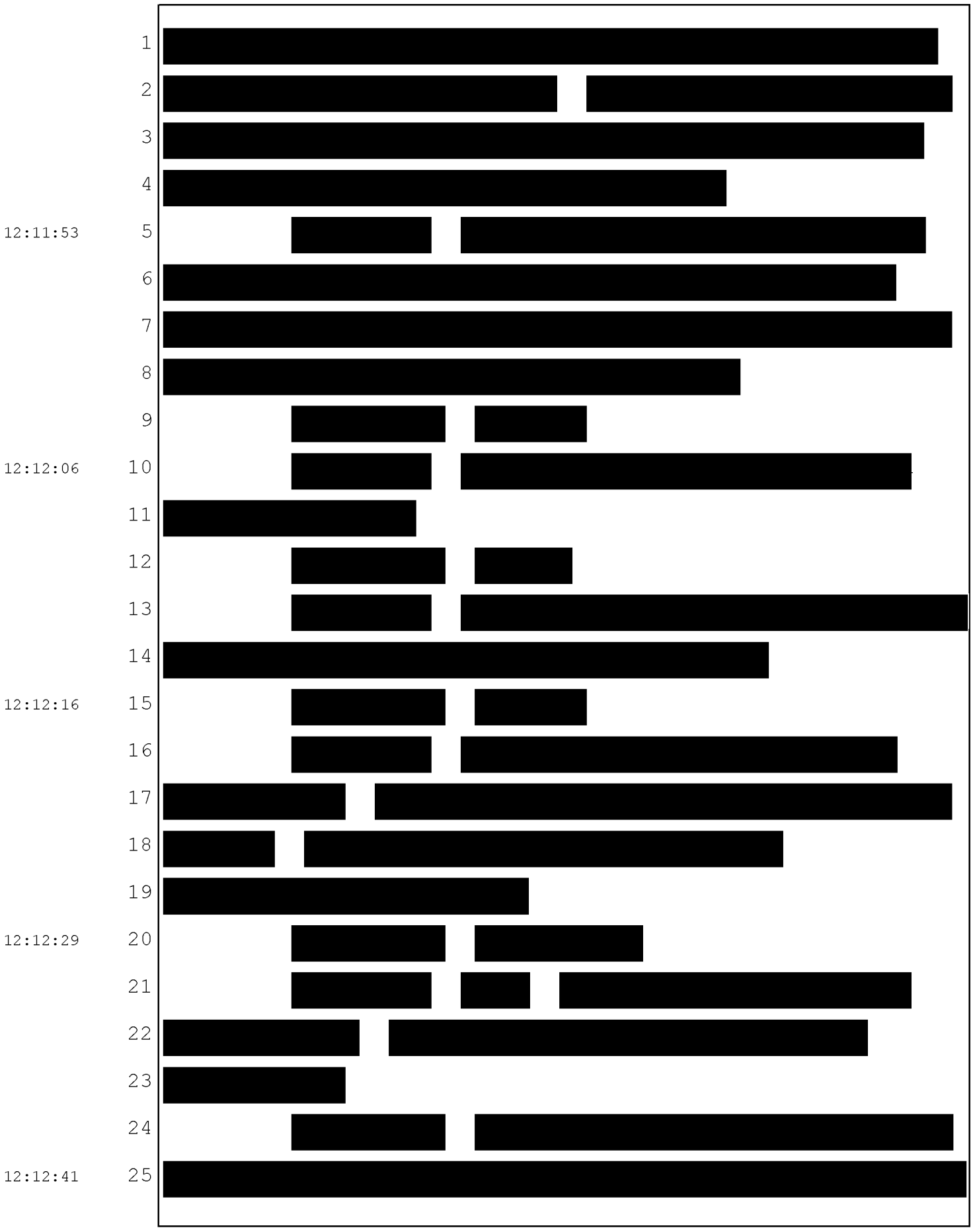
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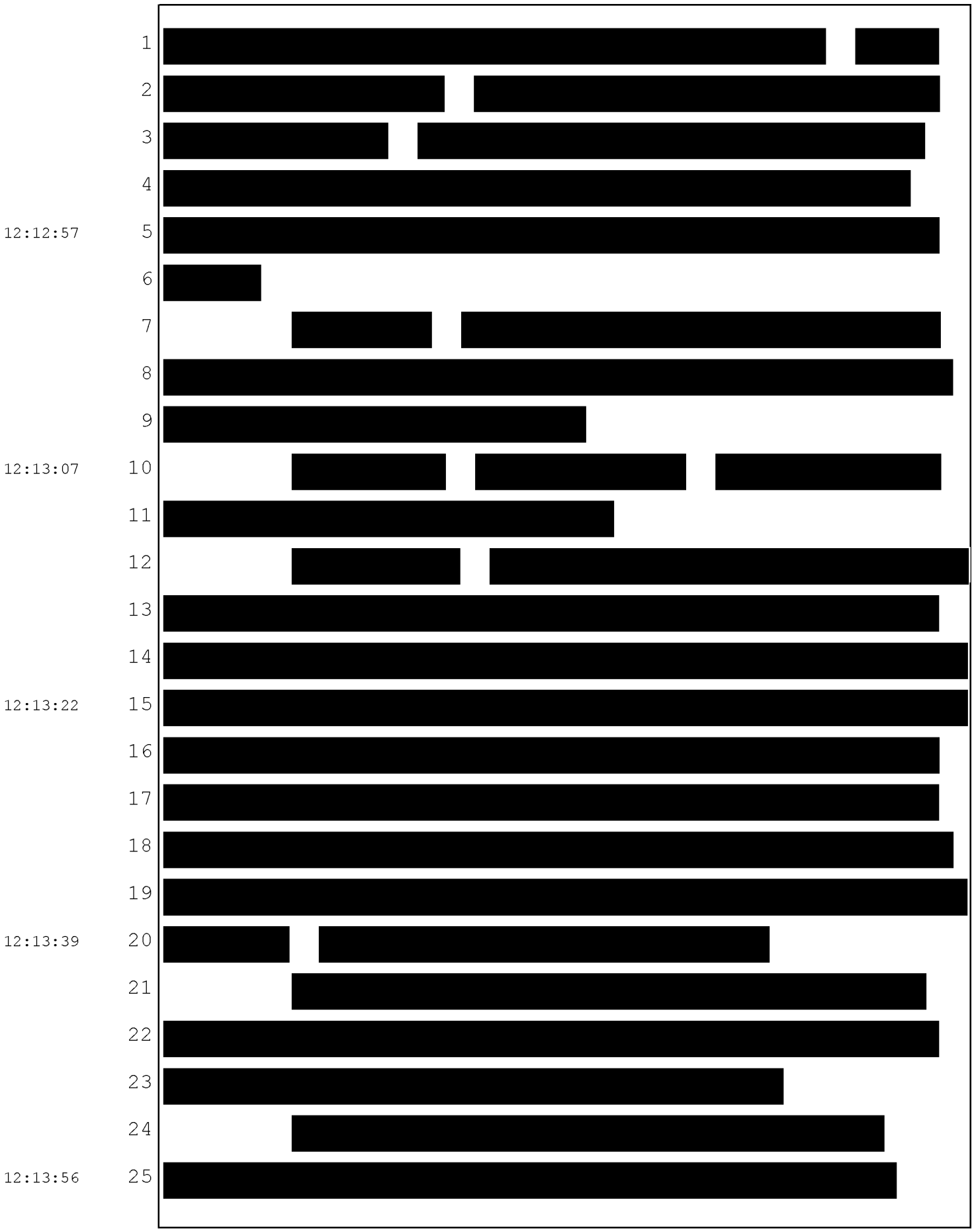
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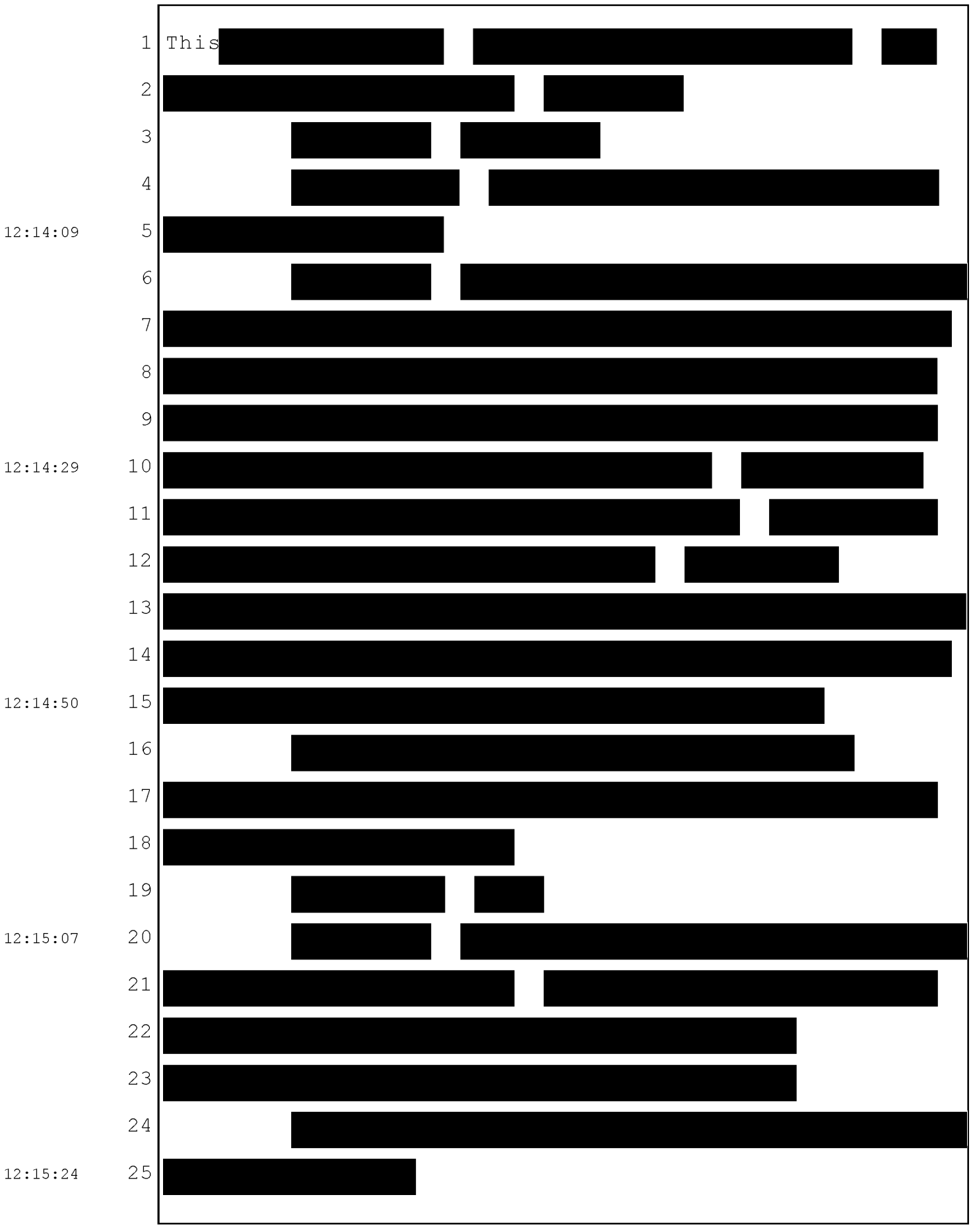
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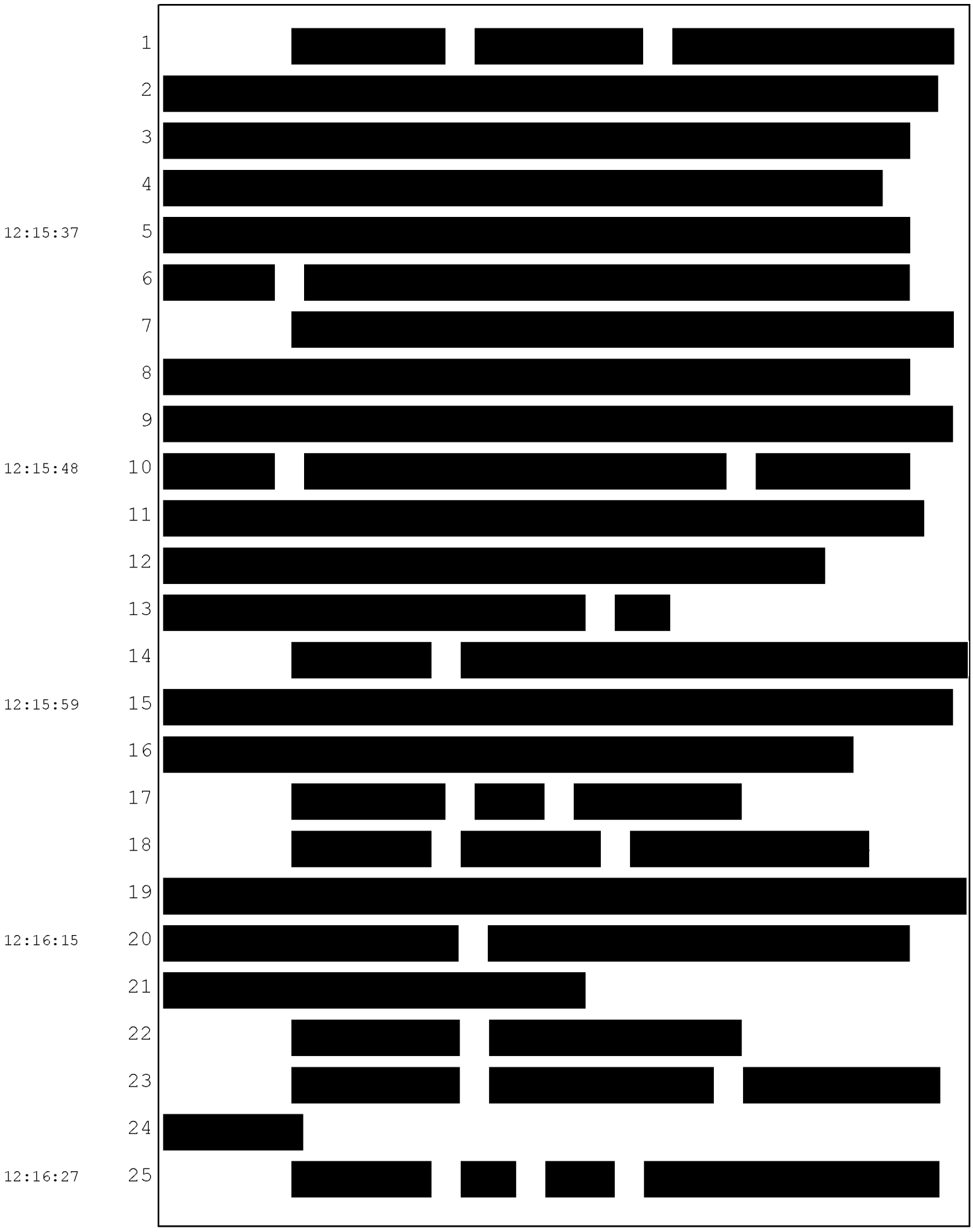
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12:18:08 (Time Noted: 12:16 p.m.)

REPORTER'S CERTIFICATE

I certify that the proceedings in the within-titled cause were taken at the time and place herein named; that the proceedings were reported by me, a duly Certified Shorthand Reporter of the State of California authorized to administer oaths and affirmations, and said proceedings were thereafter transcribed into typewriting.

I further certify that I am not of counsel or Attorney for either or any of the parties to said Proceedings, not in any way interested in the outcome of the cause named in said proceedings.

IN WITNESS WHEREOF, I have hereunto set my hand: July 12th, 2018.

<%signature%>
Leslie Rockwood Rosas
Certified Shorthand Reporter
State of California
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