

Levemir[®] (insulina detemir)
w leczeniu cukrzycy typu 2

Analiza ekonomiczna

Wersja 1.0

Kraków 2013

Wykonawca:

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Spis treści

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Streszczenie

ANALIZA EKONOMICZNA

Cel

Celem analizy była ocena zasadności ekonomicznej stosowania produktu leczniczego Levemir® (insulina detemir) w leczeniu pacjentów z cukrzycą typu 2 w warunkach polskich.

Metodyka

Analizę ekonomiczną insuliny detemir przeprowadzono z wykorzystaniem walidowanego, uniwersalnego modelu cukrzycy IMS CORE (Center of Outcomes Research), udostępnionego przez Firmę Zlecającą. Model adaptowano do warunków polskich w zakresie danych kosztowych związanych z porównywanymi strategiami terapeutycznymi, danych dotyczących polskiej populacji oraz wyników skuteczności klinicznej pochodzących z wykonanej analizy efektywności klinicznej produktu Levemir® (Aestimo 2013).

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Wykaz skrótów

95% LCL	dolna granica 95% przedziału ufności (z ang. <i>lower confidence limit</i>)
95% UCL	górną granicę 95% przedziału ufności (z ang. <i>upper confidence limit</i>)
AOTM	Agencja Oceny Technologii Medycznych
bd.	brak danych
BMI	wskaźnik masy ciała (z ang. <i>Body Mass Index</i>)
CEA	analiza kosztów-efektywności (z ang. <i>cost-effectiveness analysis</i>)
ChPL	Charakterystyka Produktu Leczniczego
CI	przedział ufności (z ang. <i>confidence interval</i>)
CMA	analiza minimalizacji kosztów (z ang. <i>cost minimization analysis</i>)
CUA	analiza kosztów-użyteczności (z ang. <i>cost-utility analysis</i>)
HRQoL	jakość życia związana ze zdrowiem (z ang. <i>health-related quality of life</i>)
HTA	ocena technologii medycznych (z ang. <i>Health Technology Assessment</i>)

JGP	Jednorodne Grupy Pacjentów
ITT	analiza zgodna z zaplanowanym leczeniem (z ang. <i>intention-to-treat</i>)
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mc.	masa ciała
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MZ	Ministerstwo Zdrowia
NFZ	Narodowy Fundusz Zdrowia
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PICO	<i>Population, Intervention, Comparator, Outcome</i>
PKB	Produkt Krajowy Brutto
PPP	perspektywa podmiotu zobowiązanego do finansowania świadczeń ze środków publicznych
PPP+P	perspektywa wspólna podmiotu zobowiązanego do finansowania świadczeń ze środków publicznych i pacjentów
PTD	Polskie Towarzystwo Diabetologiczne
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RCT	badanie kliniczne z randomizacją i grupą kontrolną (z ang. <i>randomized controlled trial</i>)
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T1DM	cukrzyca typu 1 (z ang. <i>Type 1 Diabetes Mellitus</i>)
T2DM	cukrzyca typu 2 (z ang. <i>Type 2 Diabetes Mellitus</i>)
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Analiza ekonomiczna

Rozdział

I

1.1 Cel analizy

Celem analizy była ocena zasadności ekonomicznej stosowania produktu leczniczego Levemir® (insulina detemir) w warunkach polskich w leczeniu pacjentów z cukrzycą typu 2 [REDACTED]

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1.2 Problem decyzyjny

W oparciu o wykonaną analizę problemu decyzyjnego (*Aestimo 2013a*), w pierwszym etapie analizy ekonomicznej sprecyzowano kontekst kliniczny badanej technologii, posługując się schematem PICO:

- populacja, w której dana interwencja ma być stosowana (P);
- proponowana interwencja (I);
- komparatory (C);
- efekty (wyniki) zdrowotne (O).

Kontekst kliniczny rozważany w analizach: ekonomicznej i klinicznej jest zgodny z opisanym we wniosku o finansowanie produktu leczniczego Levemir® ze środków publicznych.

1.2.1 Populacja

Zgodnie z charakterystyką produktu leczniczego *ChPL Levemir 2012*, insulina detemir jest wskazana w leczeniu cukrzycy u dorosłych, młodzieży i dzieci w wieku od 2 lat i powyżej (populacja rejestracyjna).

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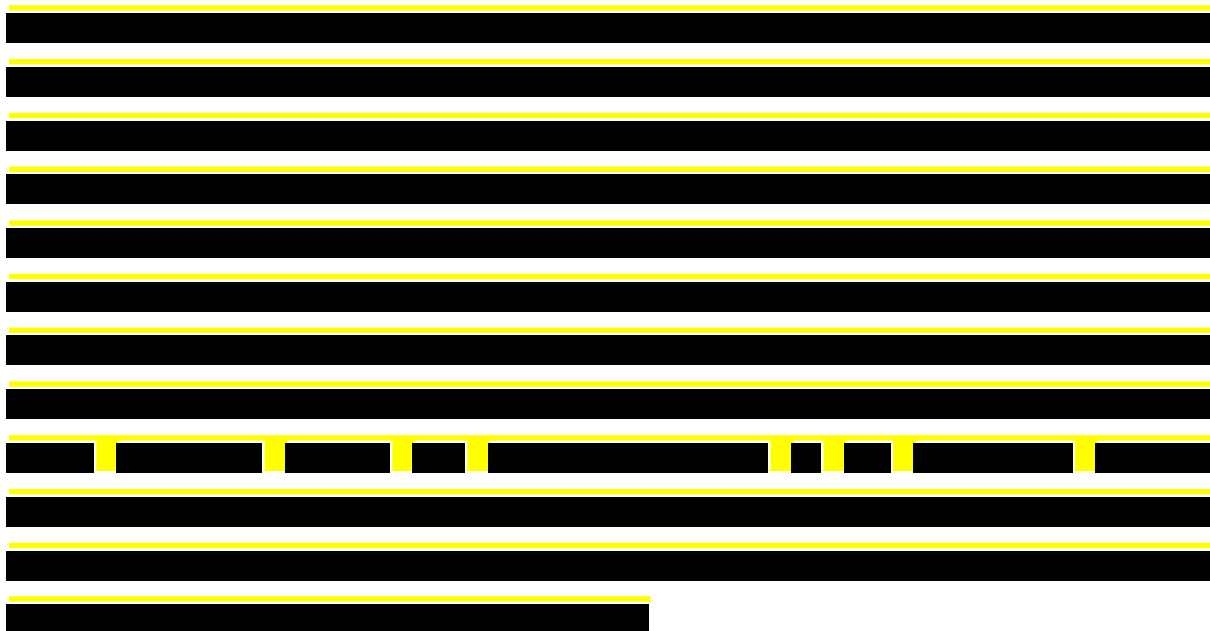
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Dane dotyczące efektywności klinicznej porównywanych strategii zaczerpnięto [REDACTED]

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1.2.2 Interwencja i komparatory

Rozważaną interwencją stanowi zastosowanie insuliny detemir (produkt leczniczy Levemir® 100 j./ml roztwór do wstrzykiwań we wkładzie; 5 wkł. a 3ml) w leczeniu chorych z cukrzycą typu 2.

Levemir® jest rozpuszczalnym, długo działającym analogiem insuliny o wydłużonym czasie działania, stosowanym jako insulina podstawowa (bazowa). Działanie insuliny detemir polegające na zmniejszeniu stężenia glukozy we krwi, występuje, gdy insulina wiąże się z receptorami w komórkach mięśniowych i tłuszczowych, ułatwiając wychwyt glukozy i hamując jednocześnie uwalnianie glukozy z wątroby.

Levemir® może być stosowany samodzielnie jako insulina bazowa (*basal*) lub w skojarzeniu z insuliną szybko działającą (*bolus*). Może także być stosowany w skojarzeniu z doustnymi lekami przeciw cukrzycowymi albo może być dodany do leczenia liraglutylem. W skojarzeniu z doustnymi lekami przeciw cukrzycowymi i po dodaniu do leczenia liraglutylem, zalecane jest stosowanie raz na dobę w dawce początkowej 10 j. lub 0,1–0,2 j./kg. Dawka produktu Levemir® powinna być dostosowywana indywidualnie do potrzeb pacjenta. Jeżeli Levemir® stosowany jest jako insulina bazowa w schemacie *basal-bolus*, powinien być podawany raz lub dwa razy na dobę w zależności od zapotrzebowania pacjenta. Dawkę produktu Levemir® należy dostosowywać indywidualnie. Levemir® jest podawany tylko podskórnice.

Dobór komparatorów dla insuliny detemir w analizie klinicznej i ekonomicznej został omówiony szeroko w analizie problemu decyzyjnego [redacted]

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1.2.3 Efekty zdrowotne

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1.2.4 Aktualny sposób finansowania leku Levemir® i wnioskowane warunki objęcia refundacją

Produkt leczniczy Levemir® jest obecnie refundowany ze środków publicznych wyłącznie we wskazanym „cukrzyca typu 1 u dorosłych, młodzieży i dzieci w wieku od 2 lat i powyżej” (MZ 22/02/2013).

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1.3 Metodyka

1.3.1 Strategia analityczna

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¹ W odniesieniu do analizy kosztów-żyteczności używa się wymiennie określenia inkrementalnego wskaźnika kosztów-efektywności – ICER.

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1.3.3 Perspektywa analizy

W analizie przyjęto perspektywę wspólną podmiotu zobowiązanego do finansowania świadczeń ze środków publicznych i pacjentów (PPP+P), a także perspektywę wyłącznie podmiotu zobowiązanego do finansowania świadczeń ze środków publicznych (PPP), uwzględniając koszty bezpośrednie związane z rozważanym problemem zdrowotnym.

W analizie nie uwzględniano kosztów pośrednich. Biorąc pod uwagę zaawansowany, zbliżony do emerytalnego wiek wyjściowy modelowanej kohorty (> 60 lat), koszty pośrednie nie stanowiłyby istotnych kosztów różniących, w związku z czym pominięcie perspektywy społecznej nie ogranicza wnioskowania z analizy.

1.3.4 Horyzont czasowy

Cukrzyca typu 2 jest chorobą przewlekłą, wymagającą przez większość czasu jej trwania zaangażowania zasobów systemu ochrony zdrowia. W związku z tym w analizie podstawowej kosztów-żyteczności przyjęto dożywotni horyzont czasowy, zalecany przez polskie wytyczne oceny technologii medycznych w przypadku technologii medycznych, których wyniki i koszty ujawniają się w ciągu całego życia chorego (AOTM 2010). Biorąc pod uwagę średni wyjściowy wiek chorych w rozważanej kohorcie (ok. 60 lat), w modelu przyjęto horyzont 35 lat jako odpowiadający w przybliżeniu horyzontowi dożywotniemu.

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1.3.5 Dyskontowanie

W analizie podstawowej przyjęto stopę dyskontową na poziomie 5% rocznie dla kosztów i 3,5% dla wyników zdrowotnych, a w analizie wrażliwości uwzględniono następujące warianty dyskontowania:

- koszty i wyniki zdrowotne: 5%;
- koszty: 5%, wyniki zdrowotne: 0%;
- brak dyskontowania kosztów i wyników zdrowotnych.

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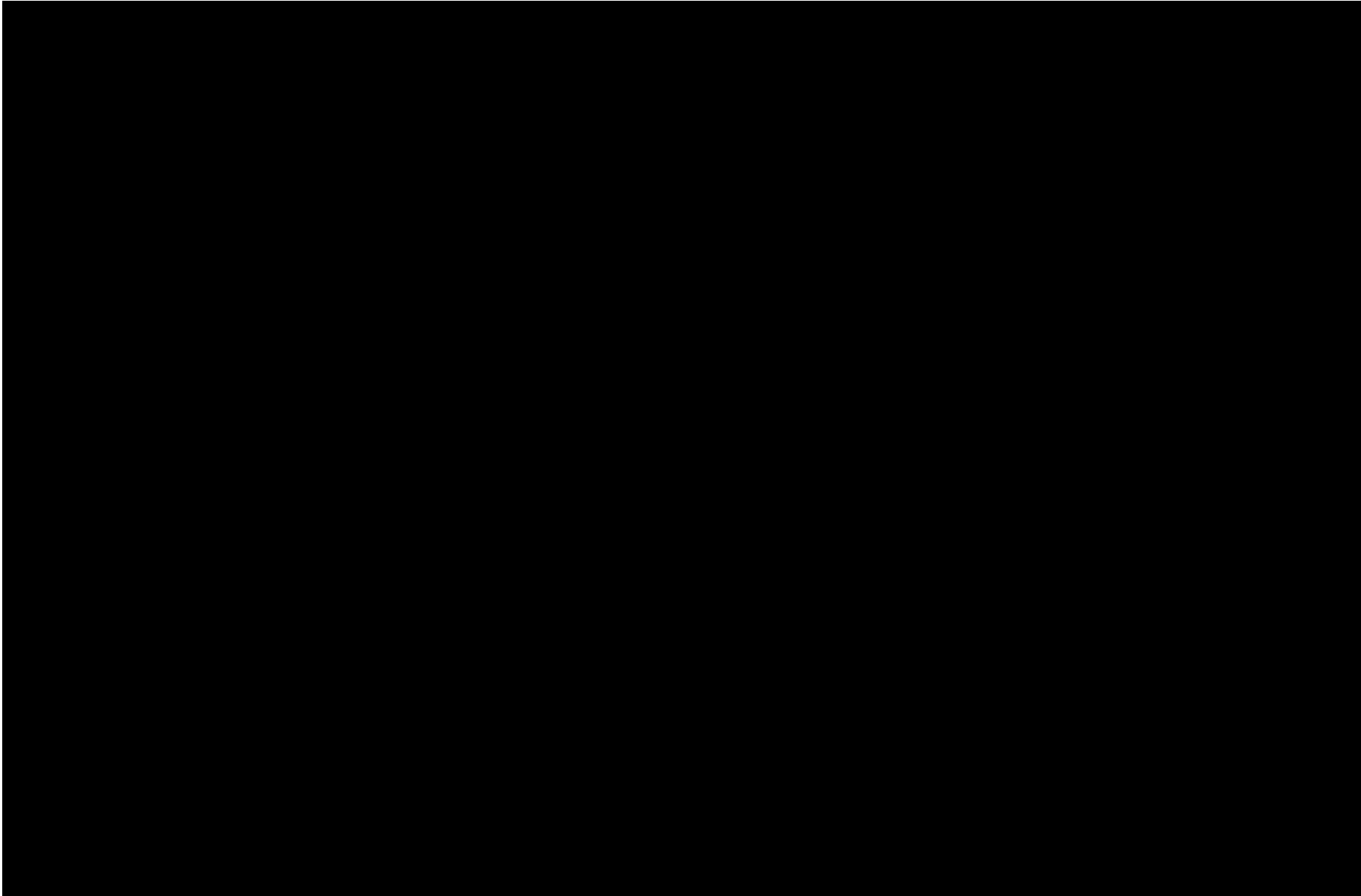
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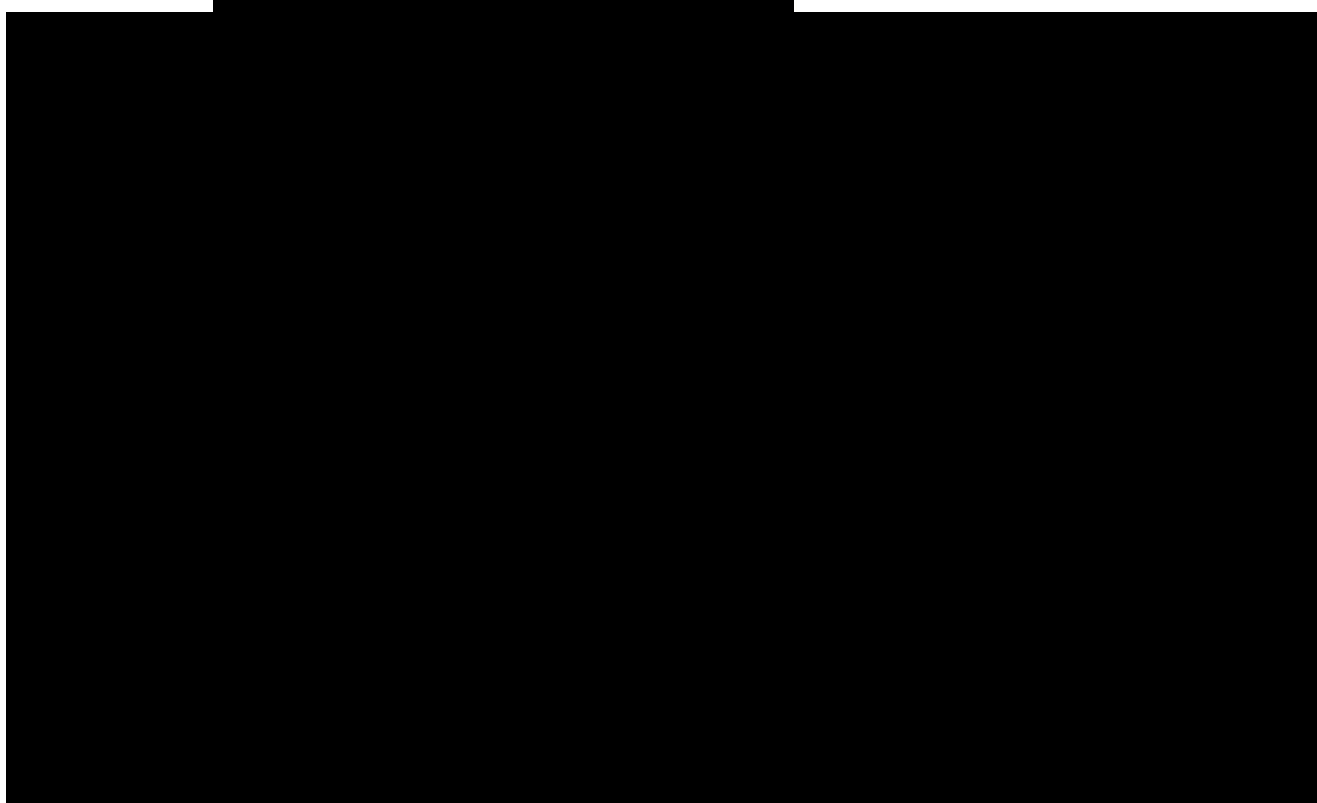
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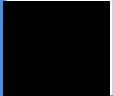
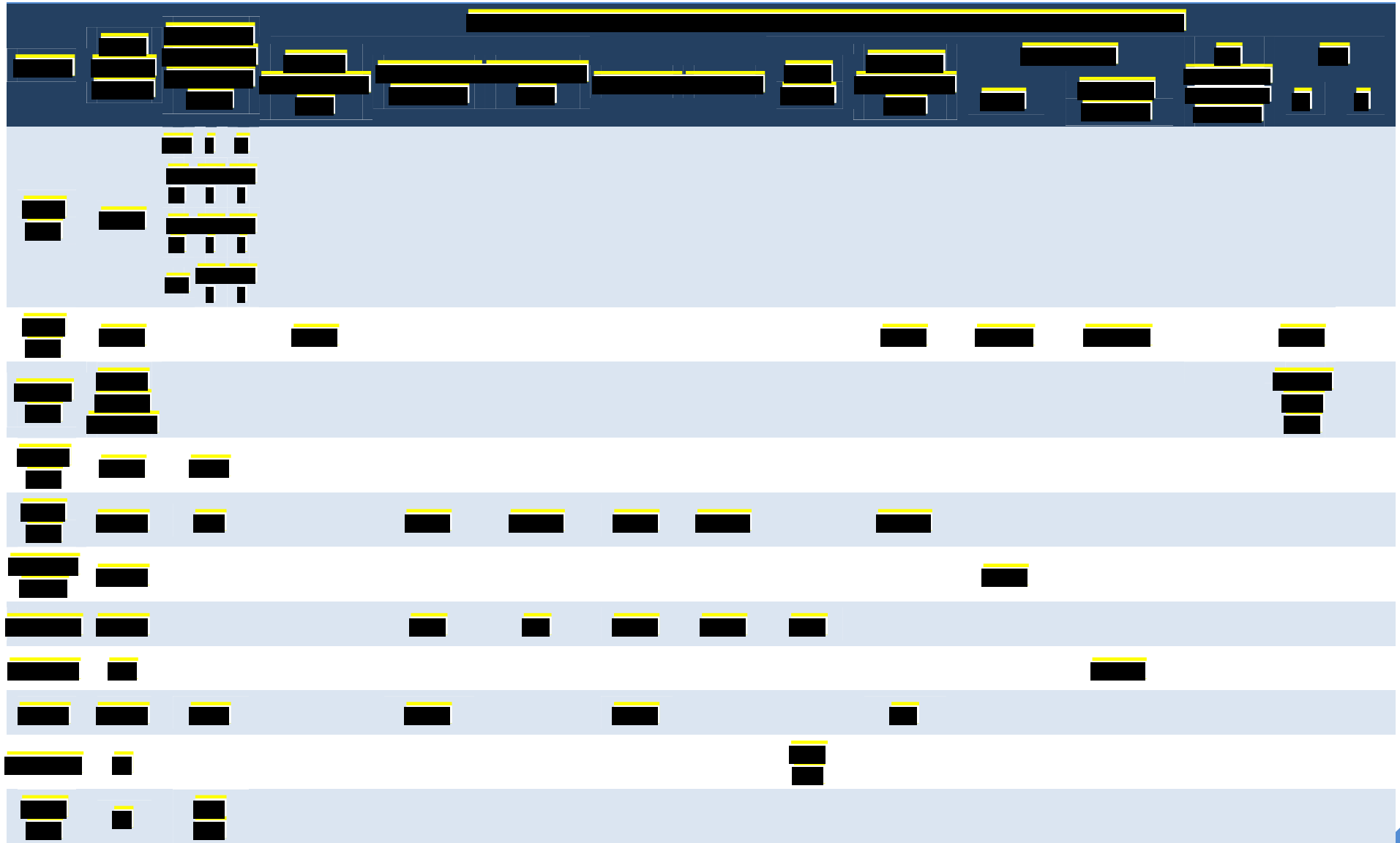
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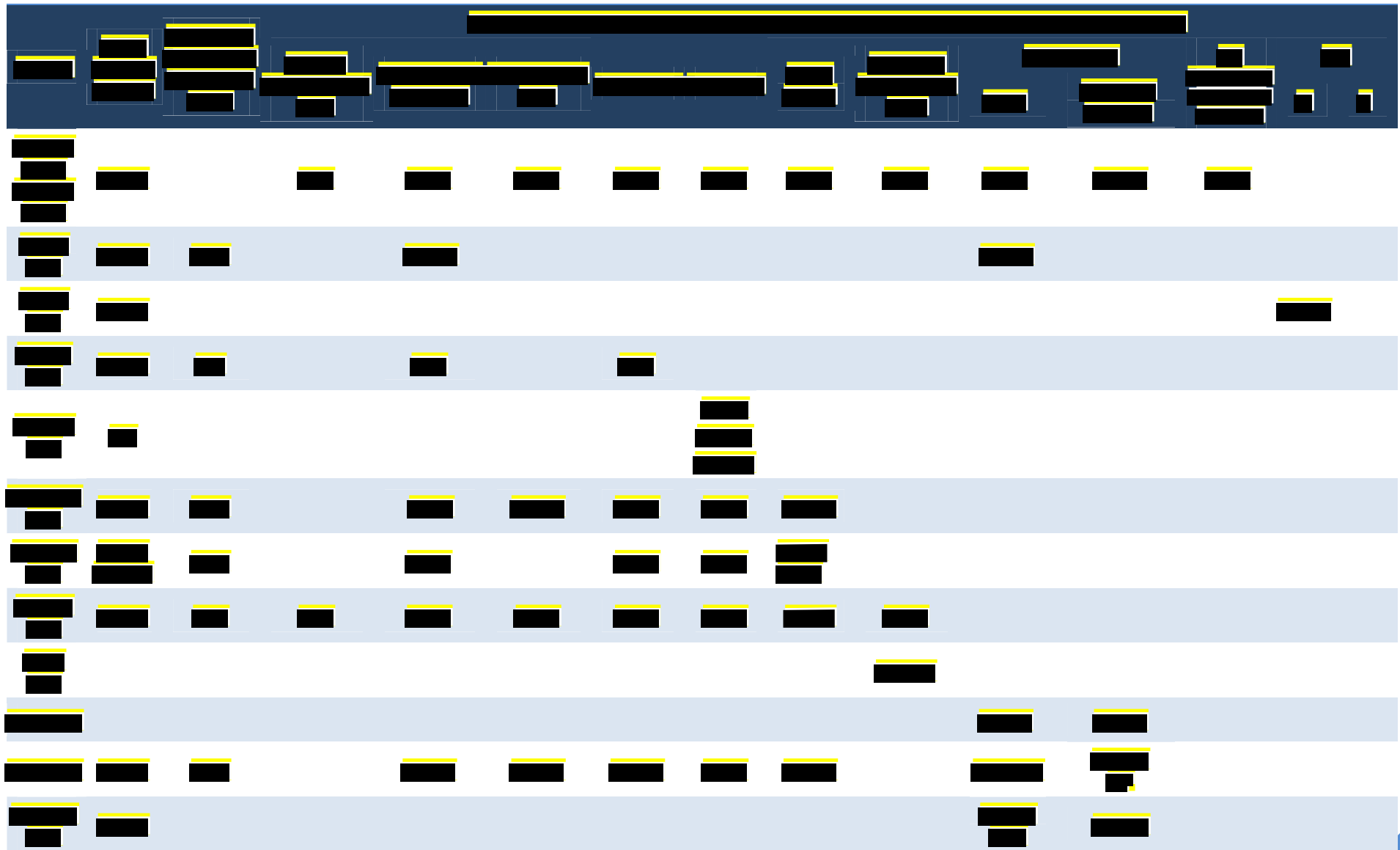
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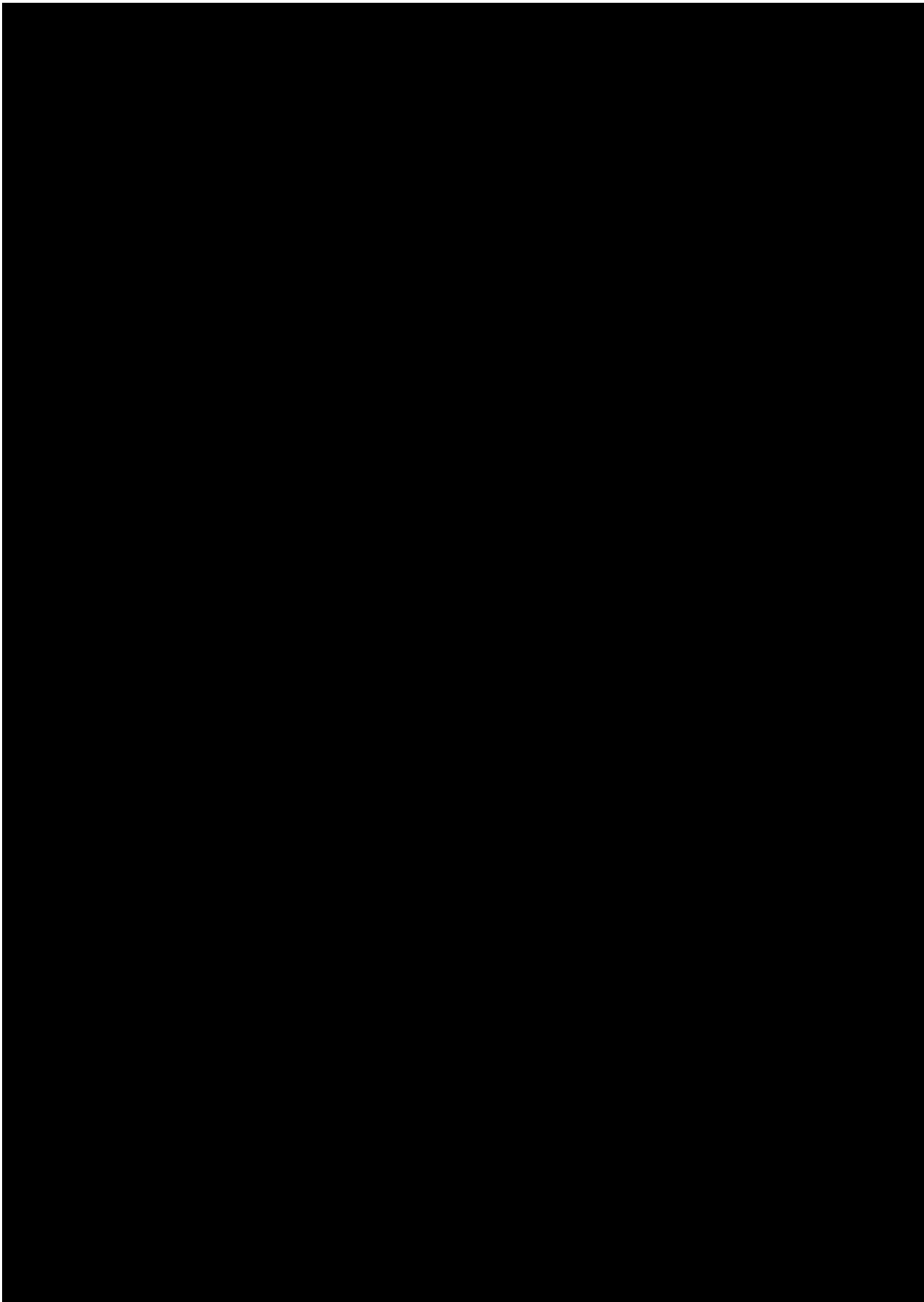
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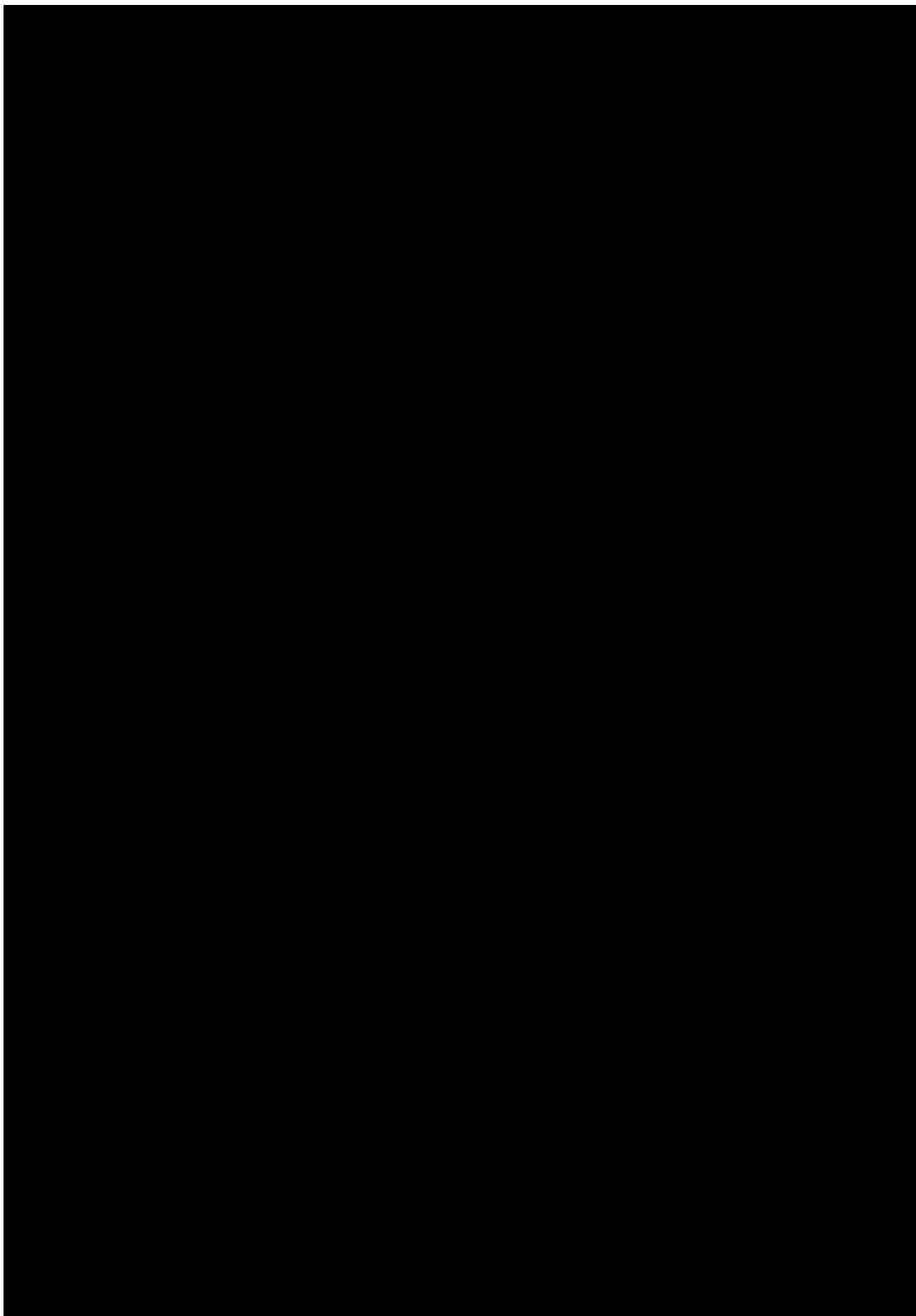
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1.4 Analiza podstawowa

Zgodnie z minimalnymi wymaganiami dotyczącymi analiz oceny technologii medycznych, przedstawionymi w Rozporządzeniu Ministra Zdrowia z dnia 2 kwietnia 2012 r. (MZ 02/04/2012), w ramach analizy podstawowej przedstawiono kolejno:

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Analizę podstawową przeprowadzono równolegle w dwóch wariantach:

- z perspektywy podmiotu zobowiązanego do finansowania świadczeń ze środków publicznych (PPP);
- z perspektywy wspólnej podmiotu zobowiązanego do finansowania świadczeń ze środków publicznych i świadczeniobiorcy (PPP+P).

1.4.1 Zestawienie oszacowań kosztów i wyników zdrowotnych

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1.4.1.1 Zestawienie kosztów

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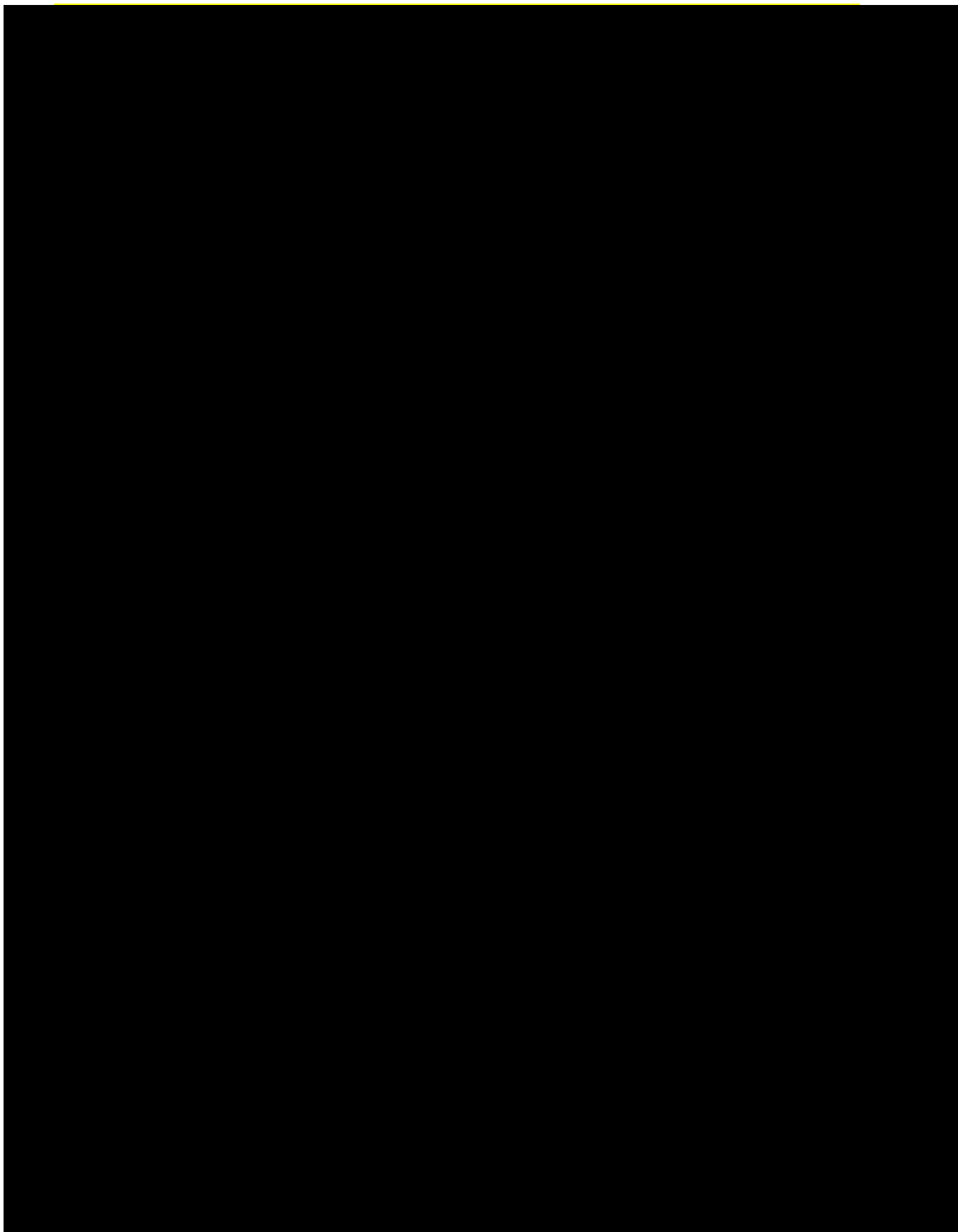
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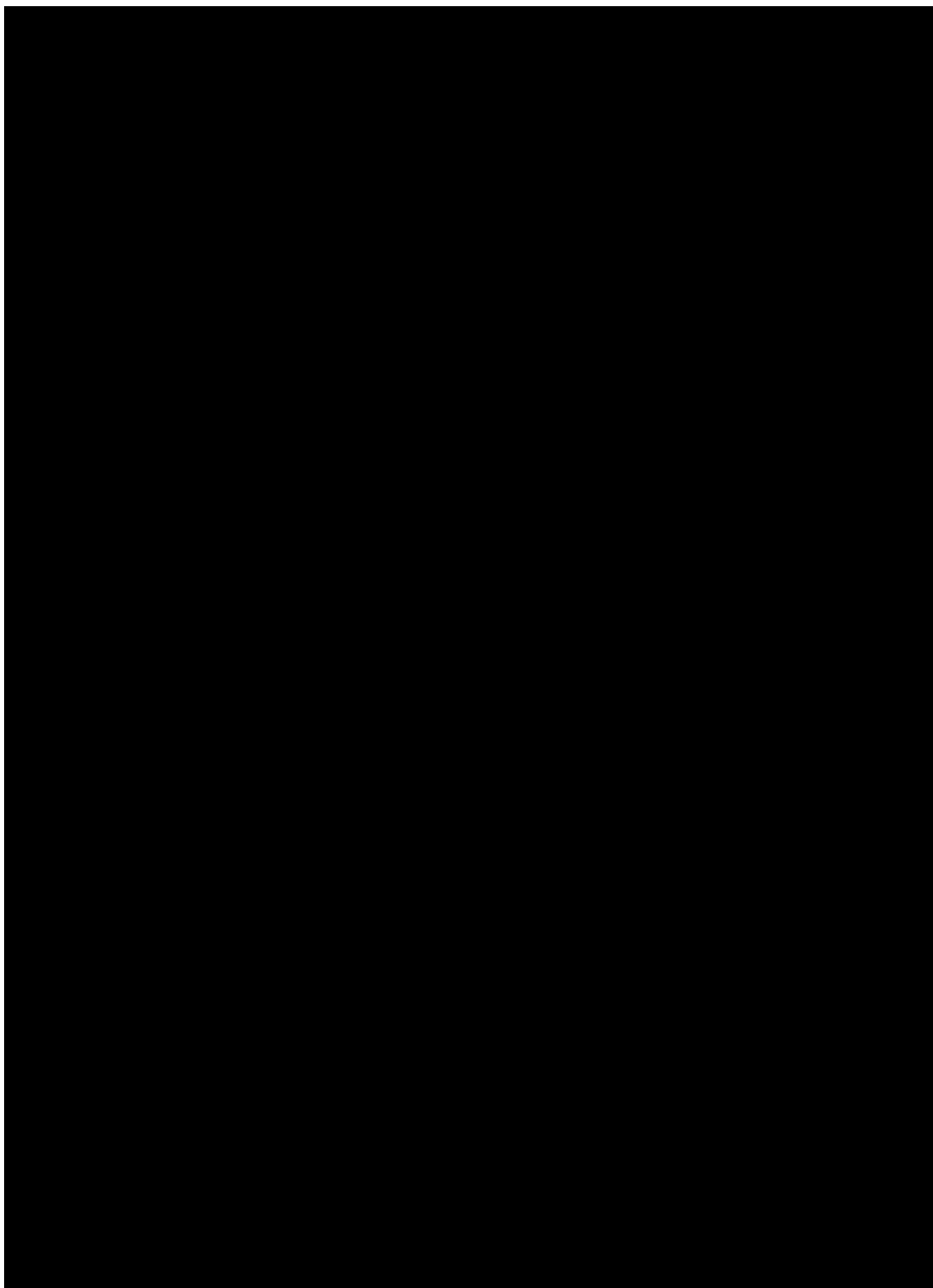
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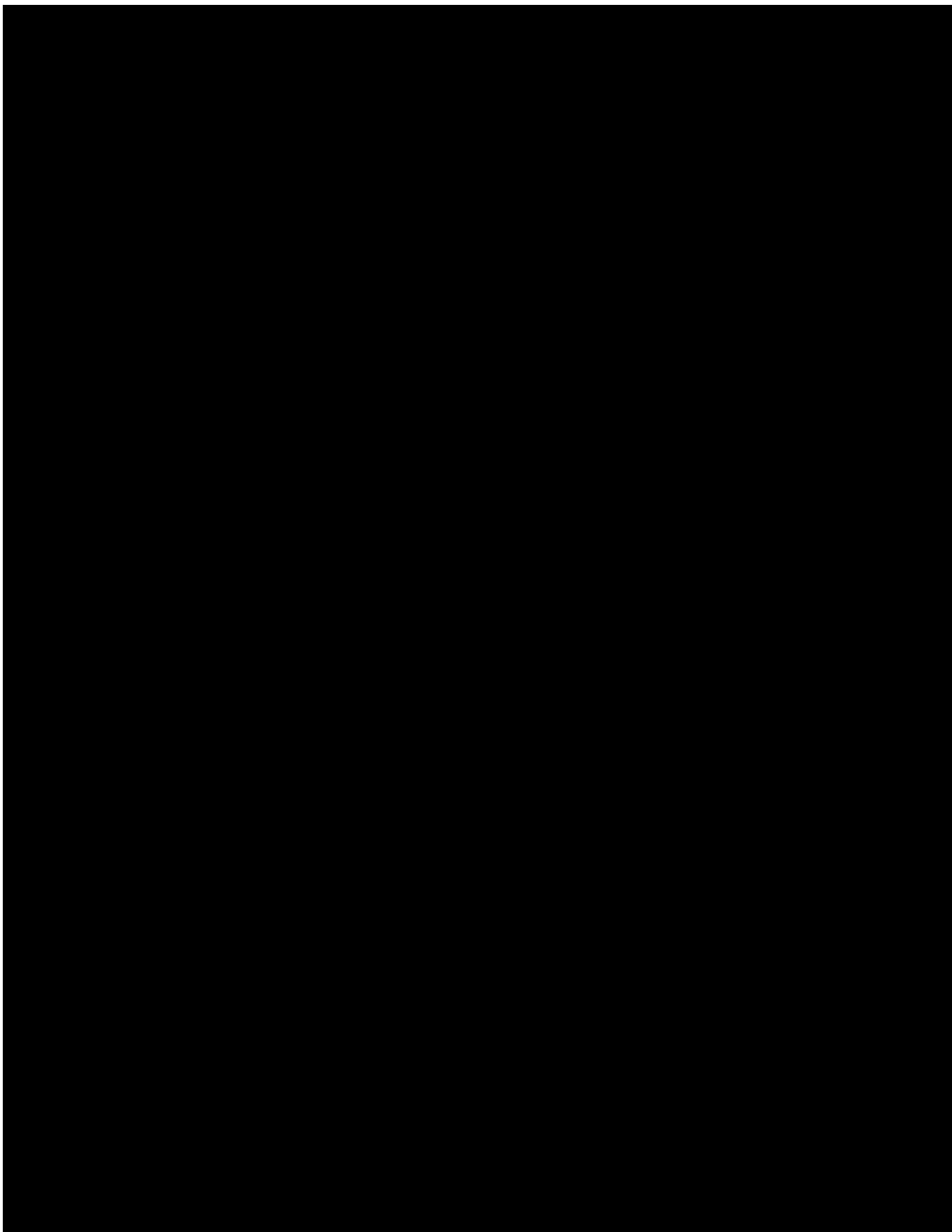
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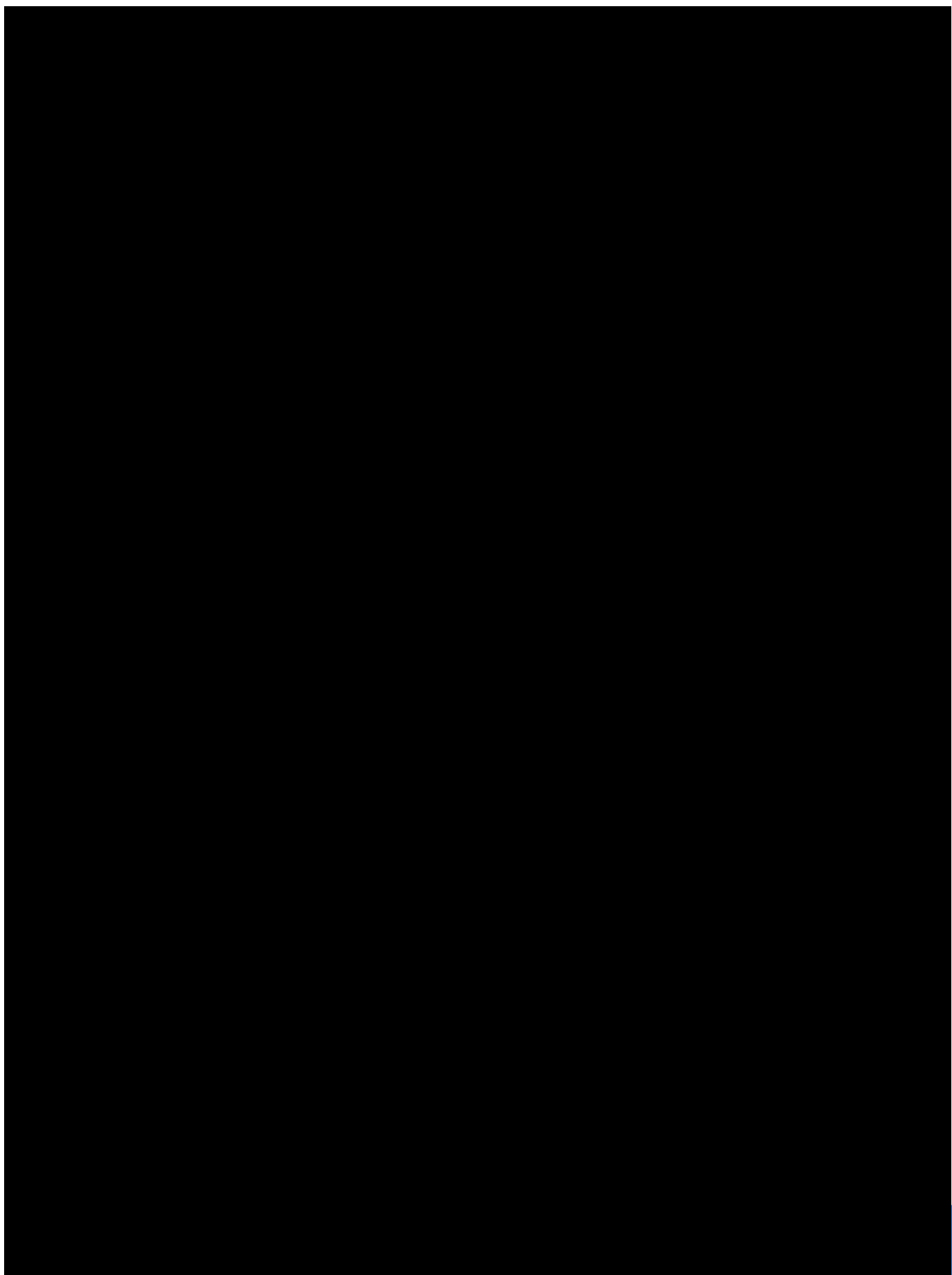
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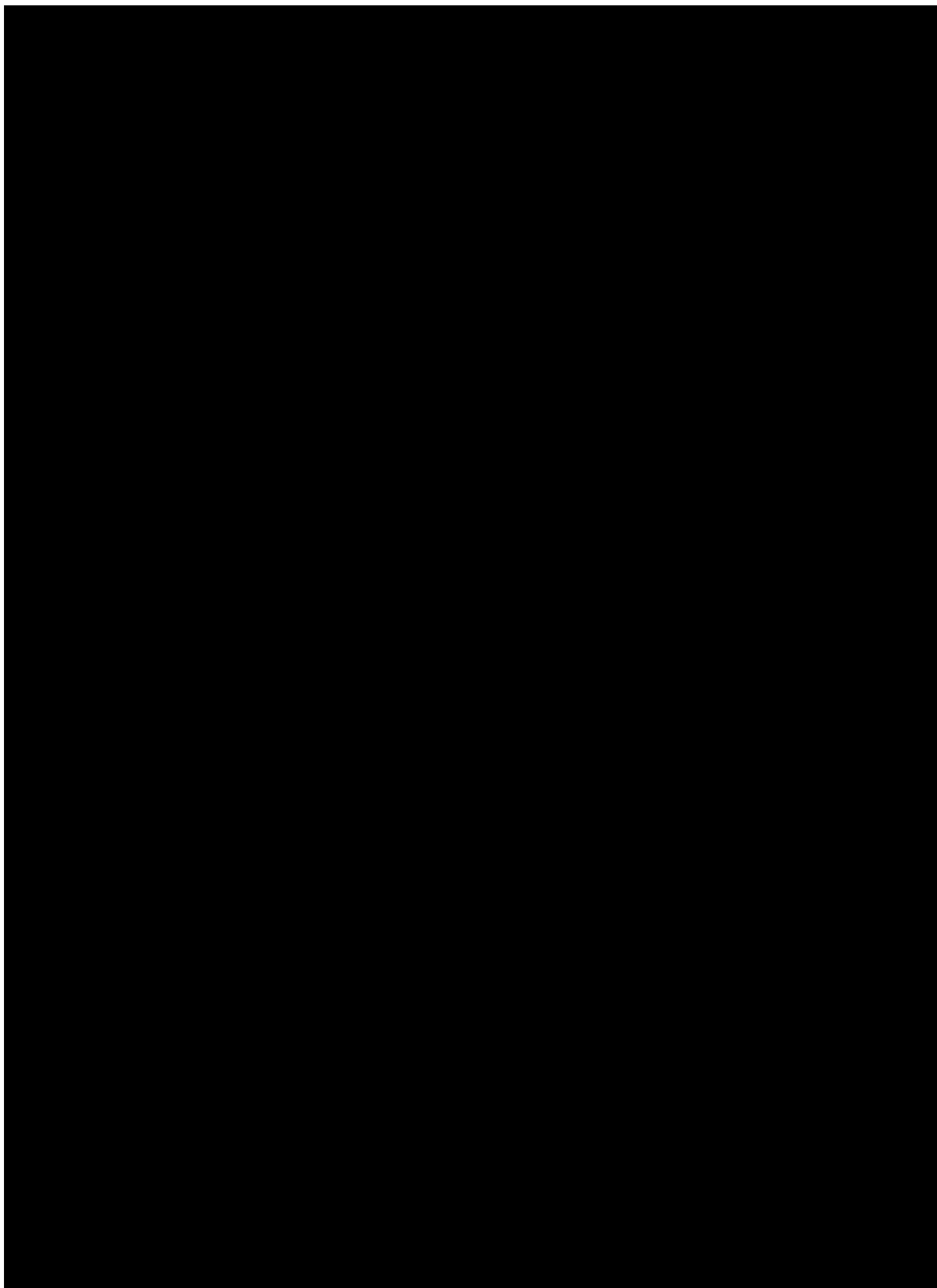
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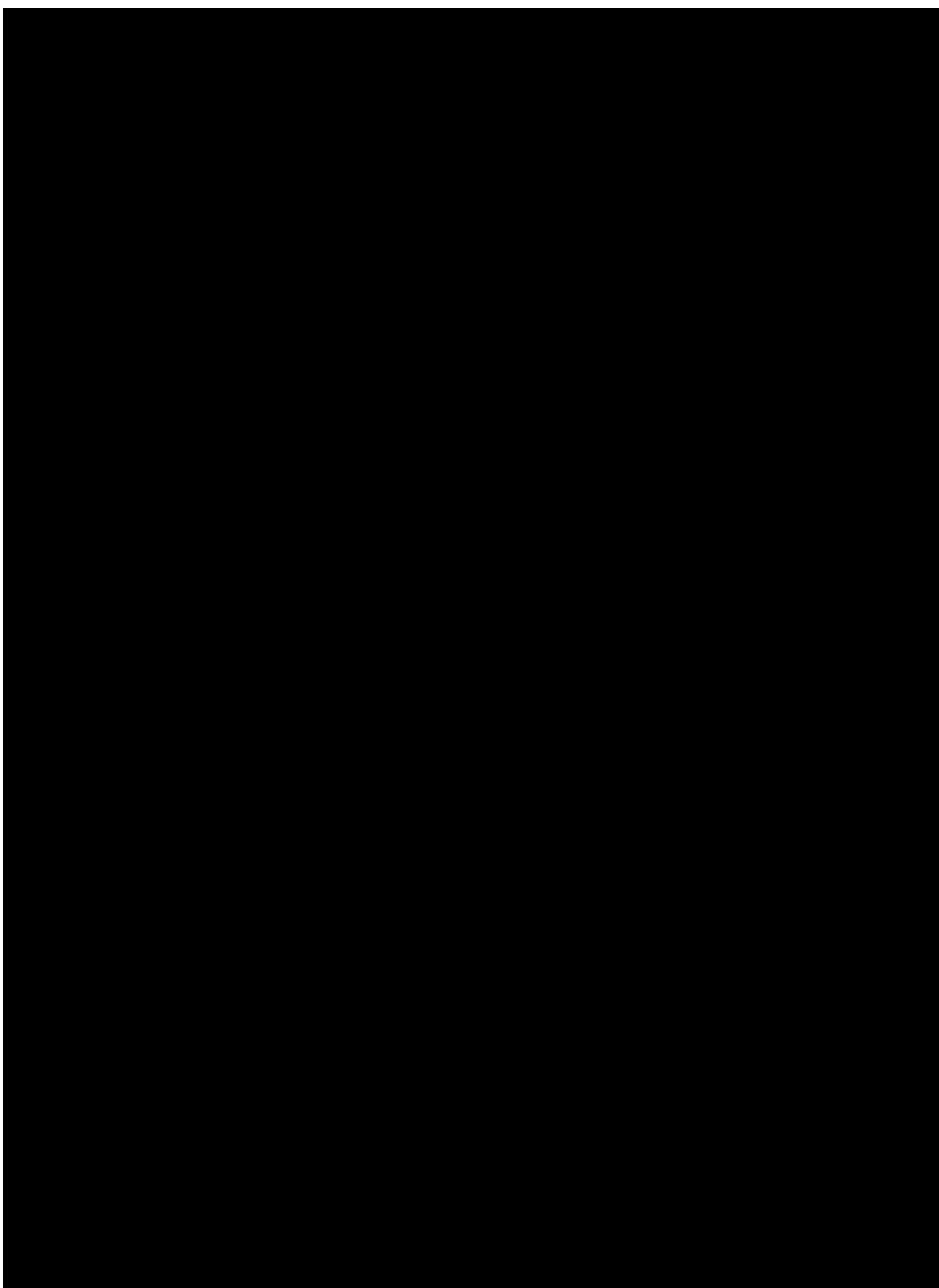


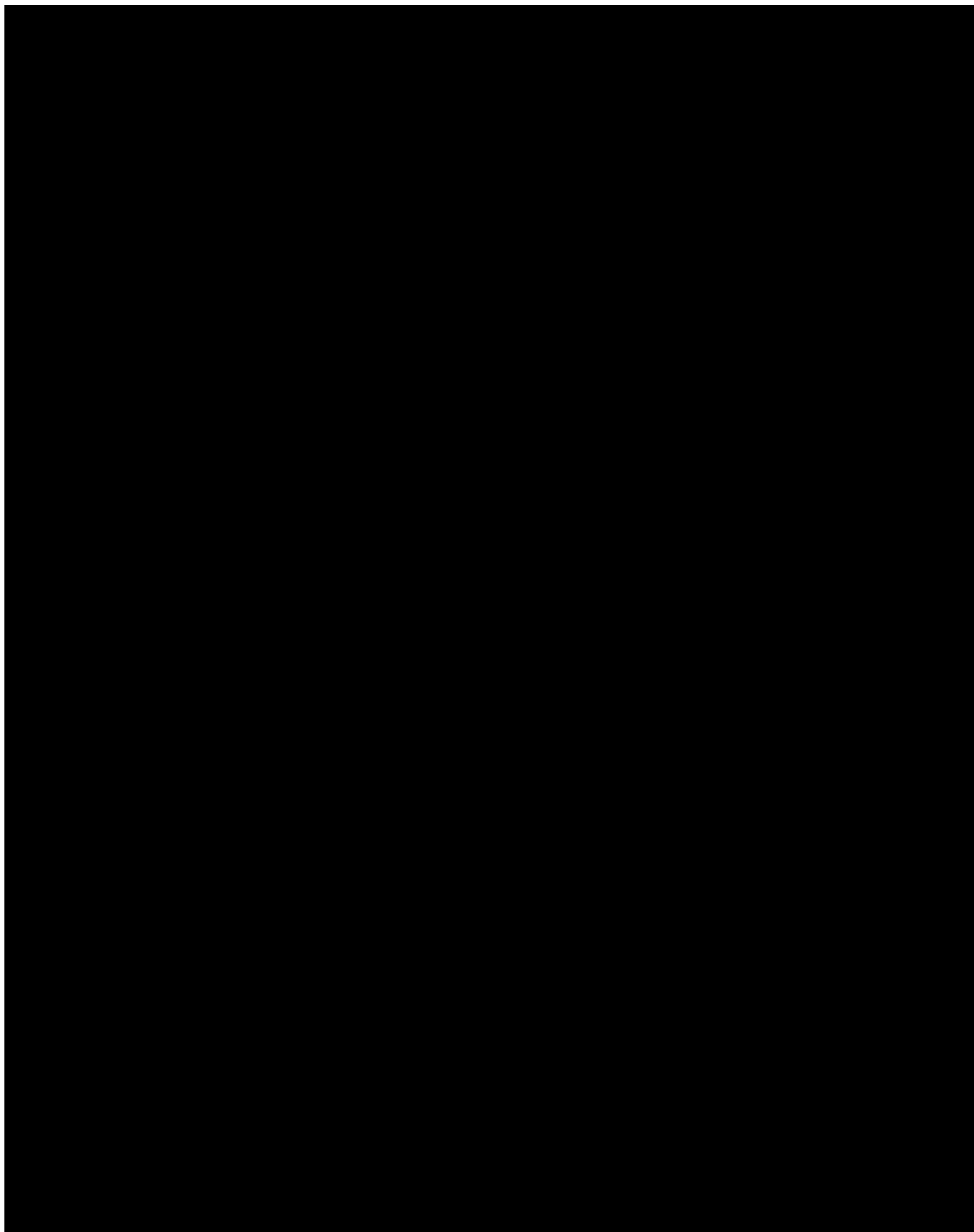


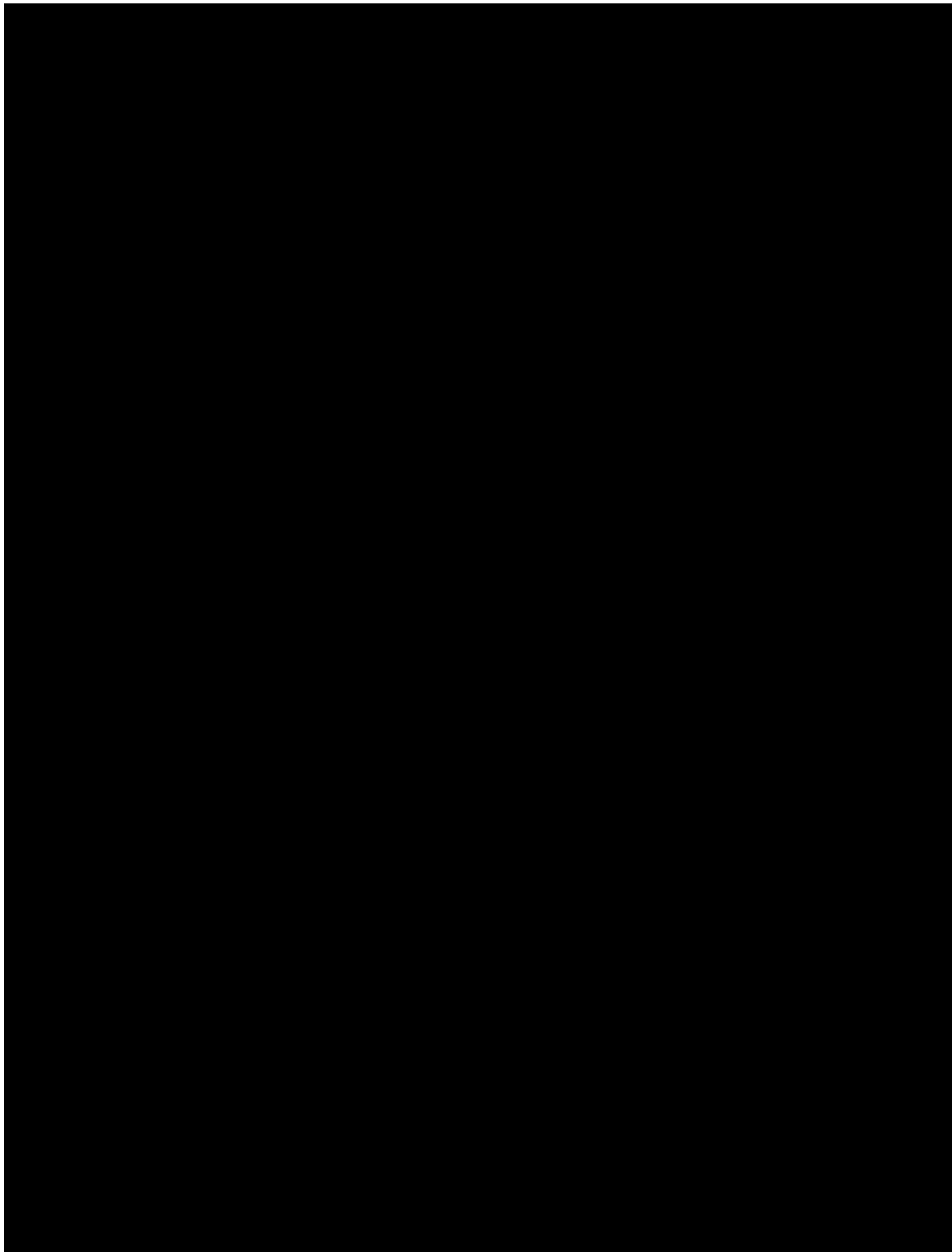












1.4.1.2 Zestawienie wyników zdrowotnych

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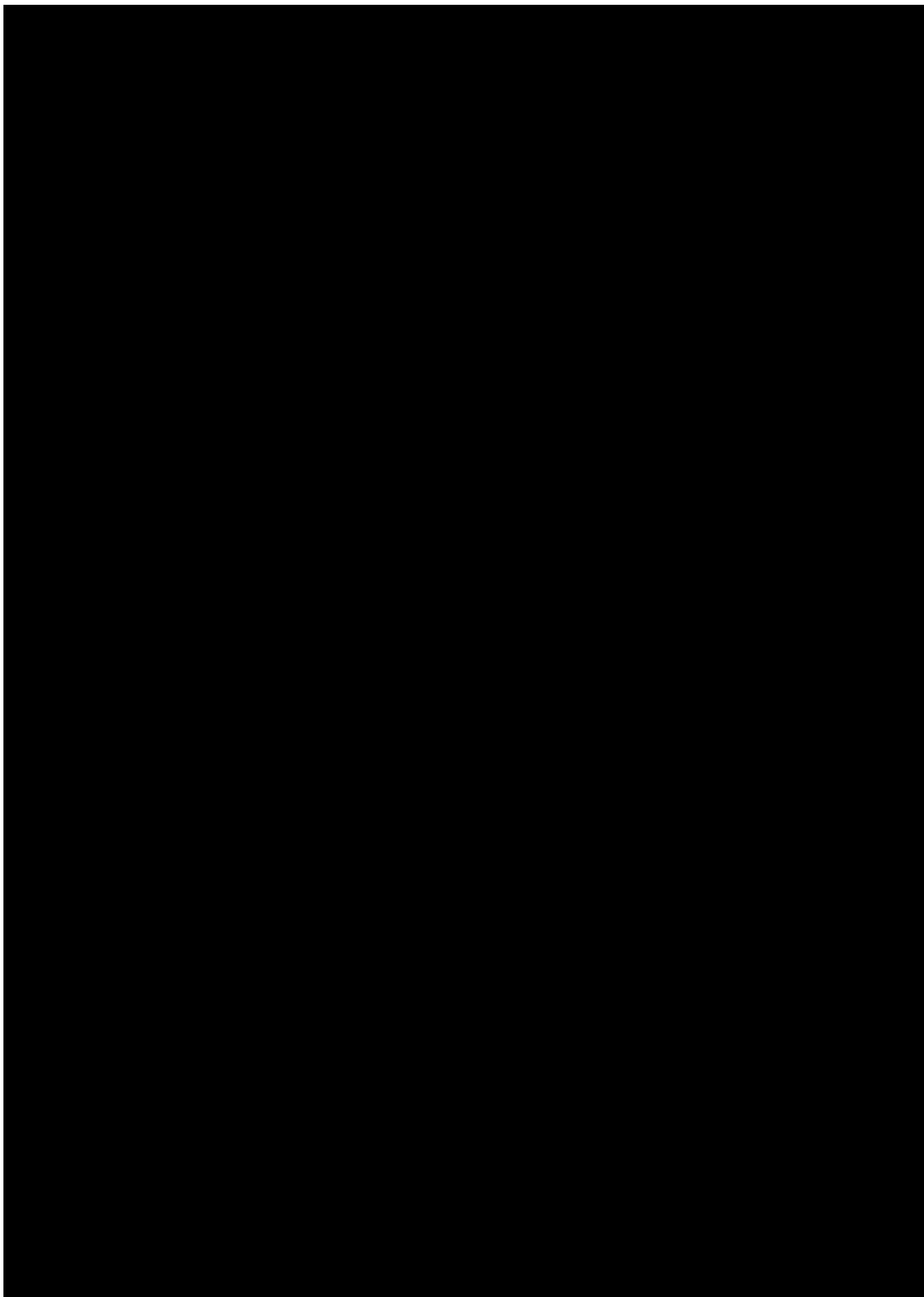
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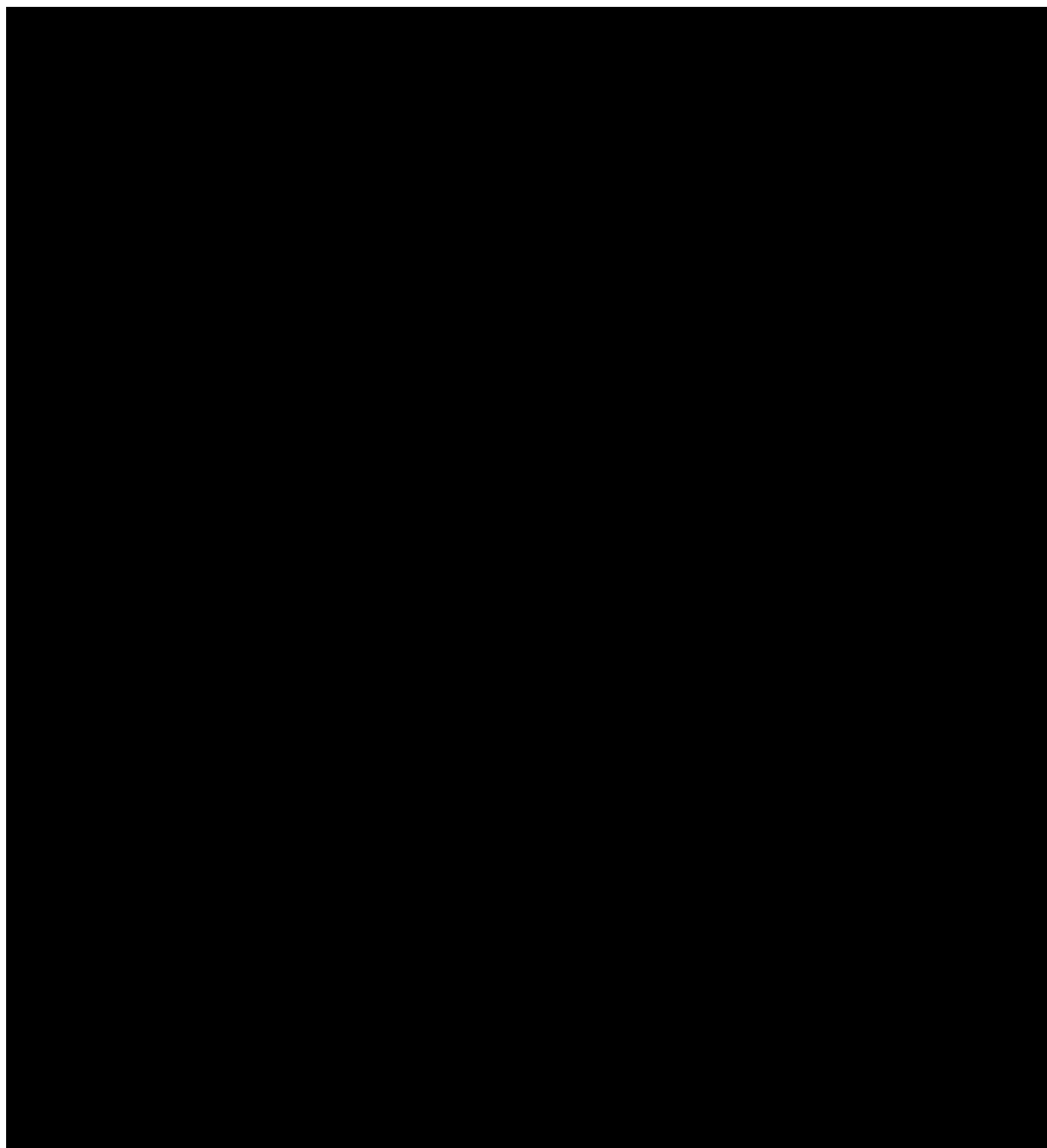
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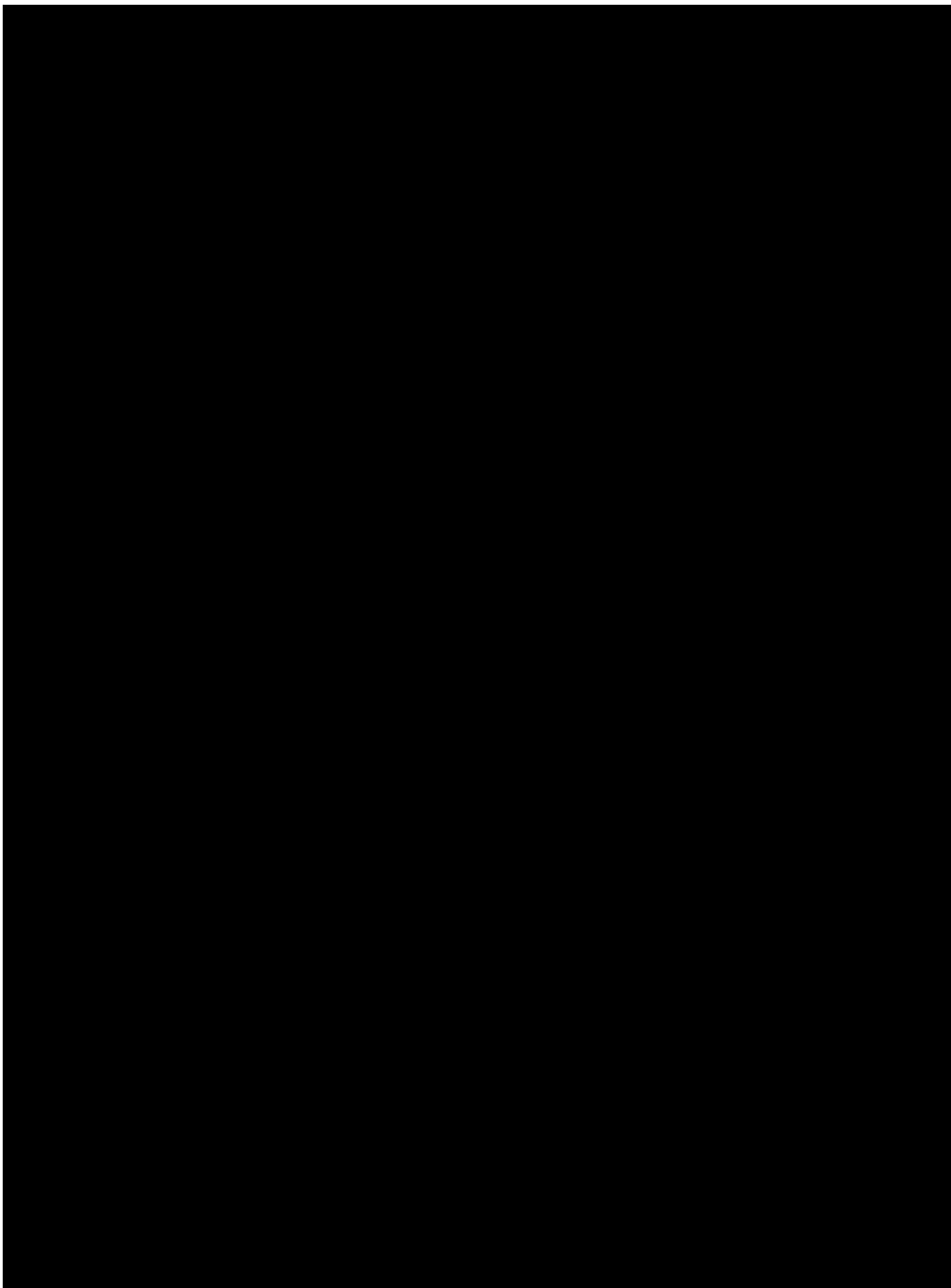
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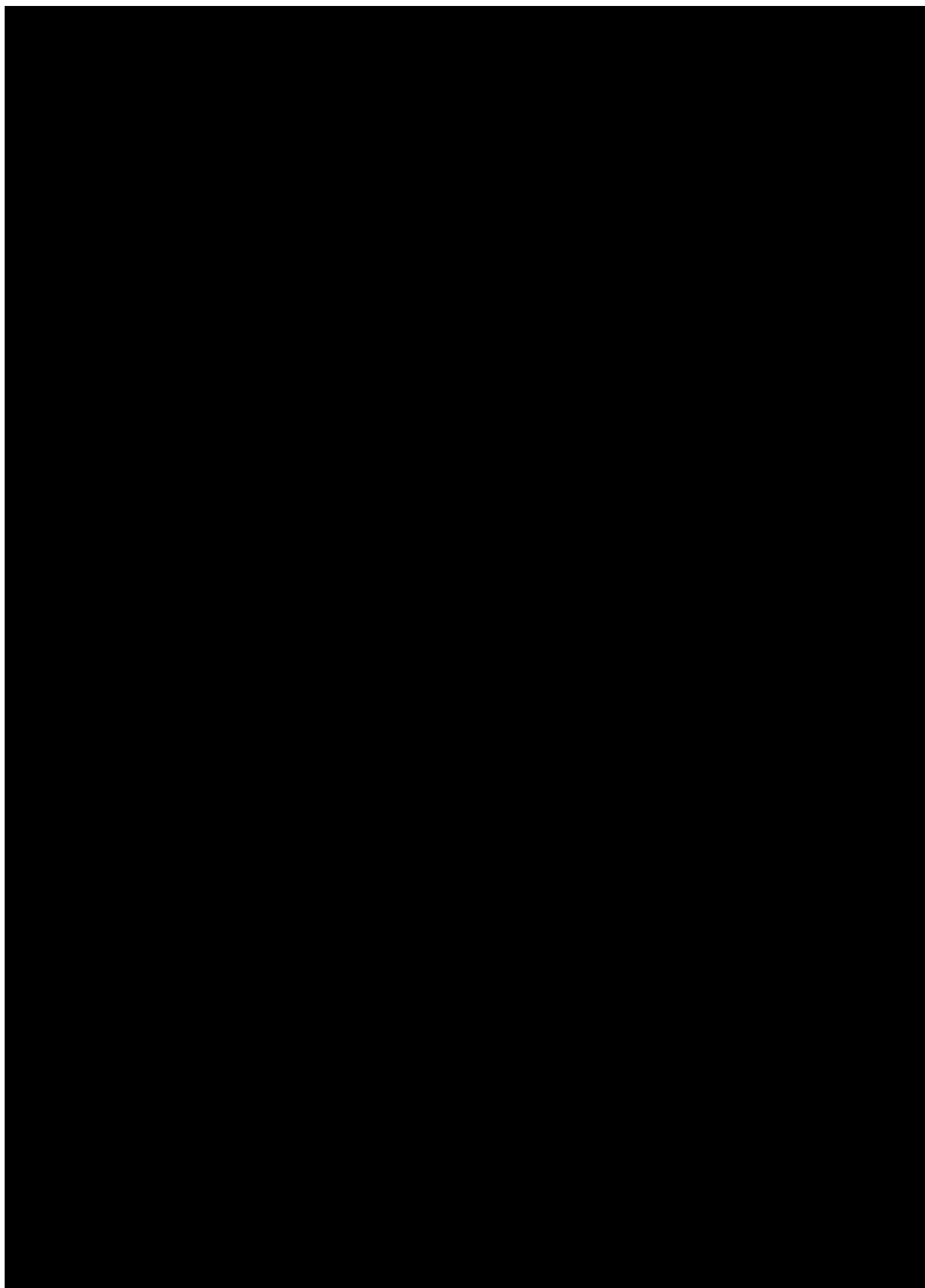
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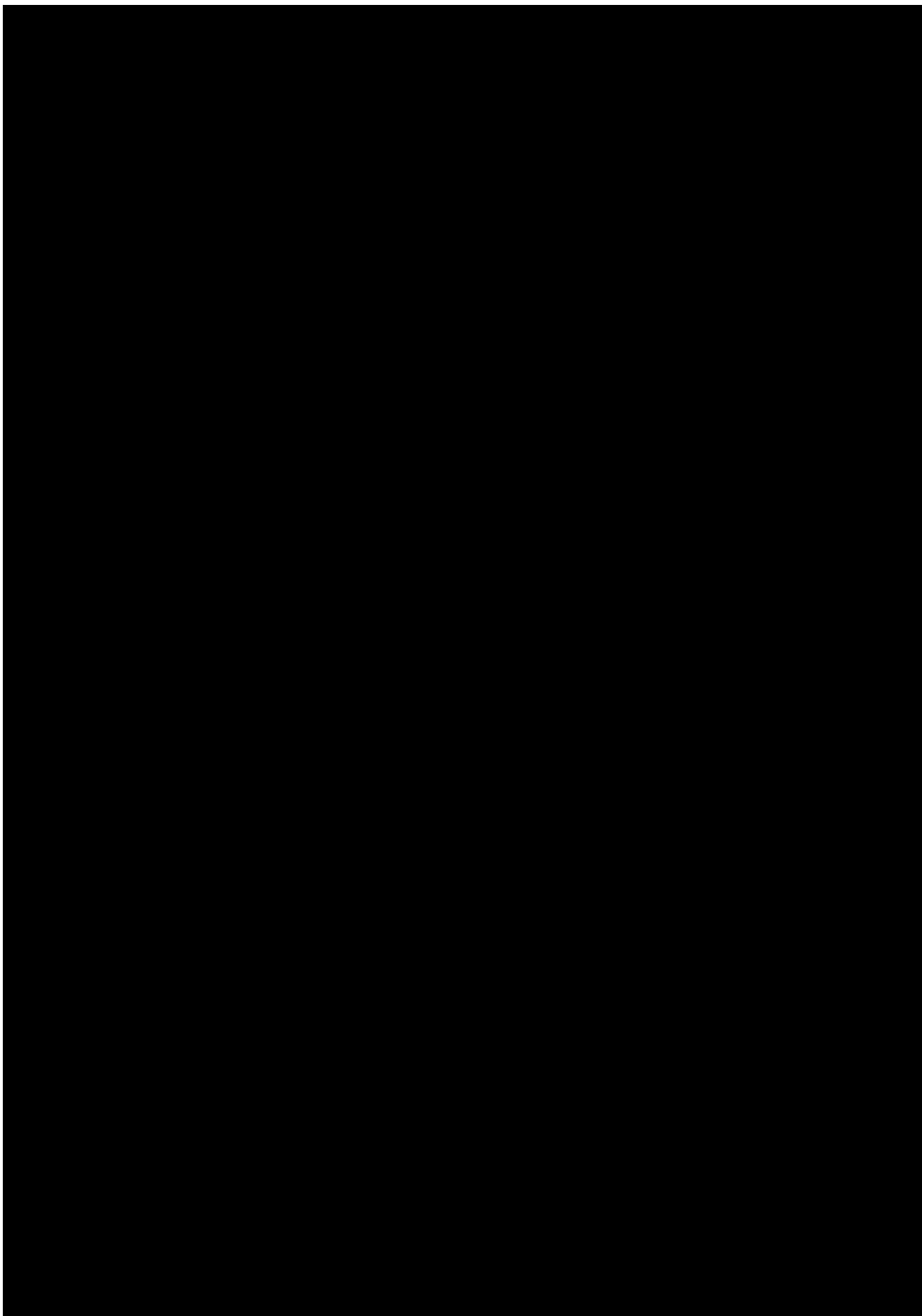
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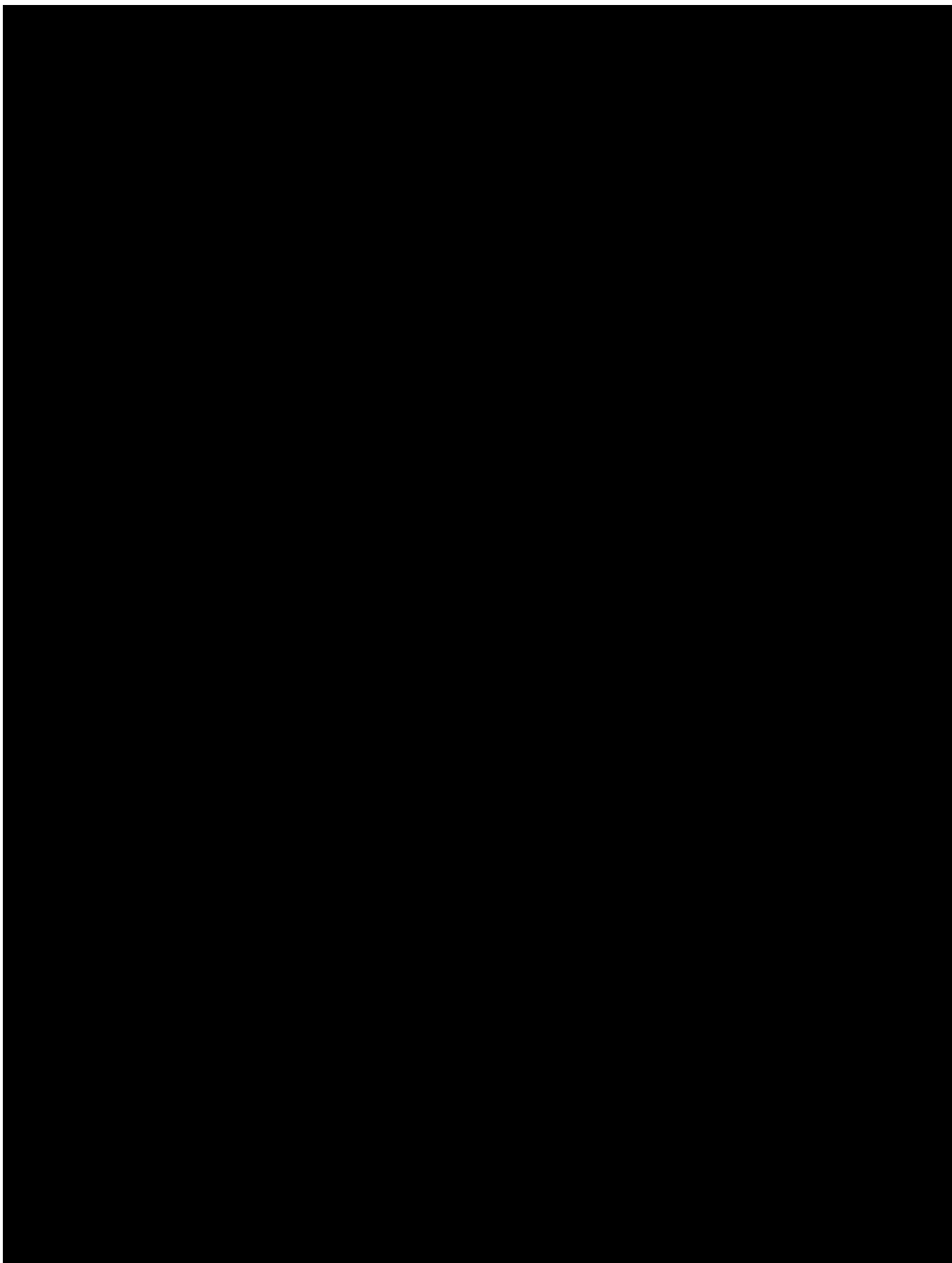


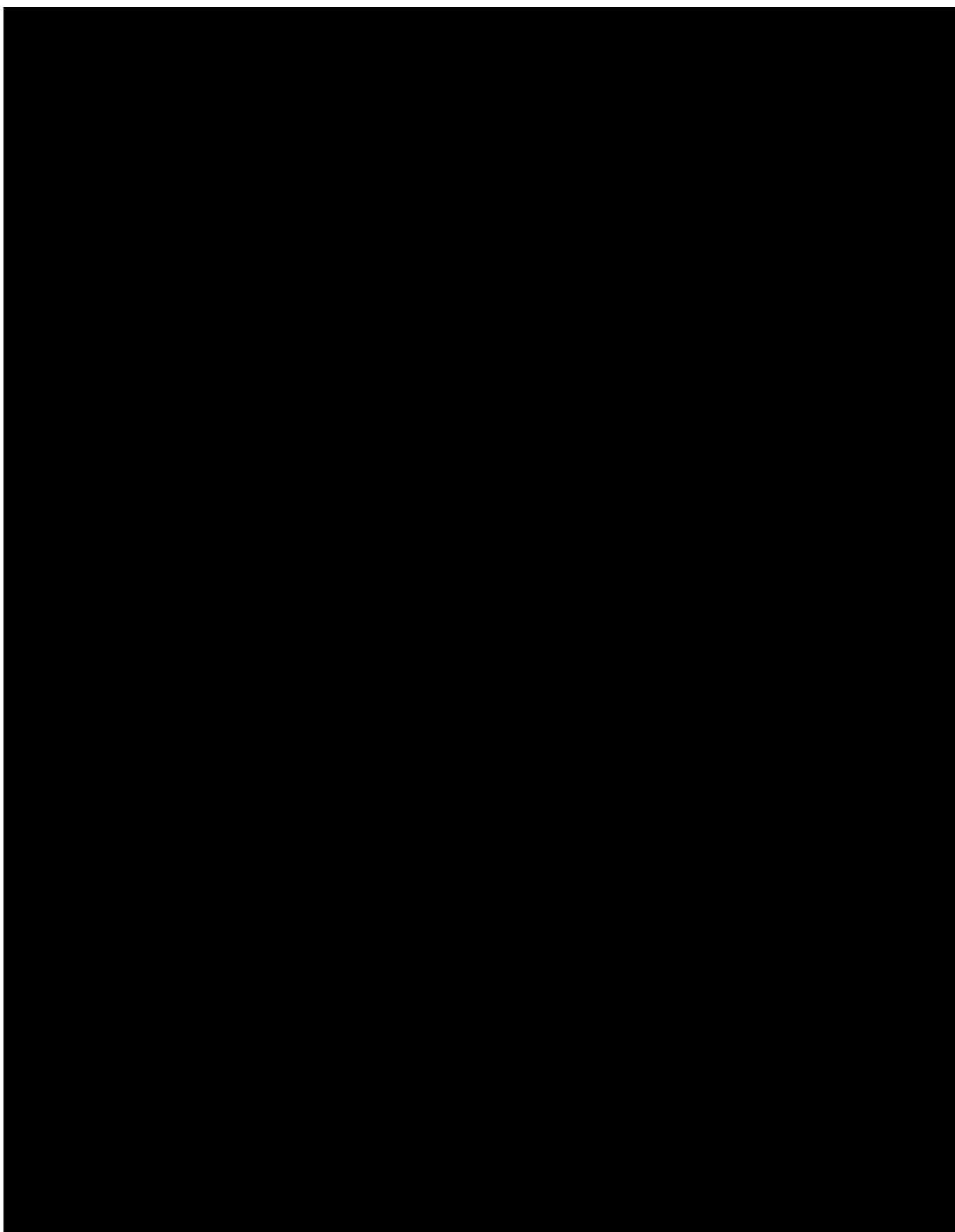


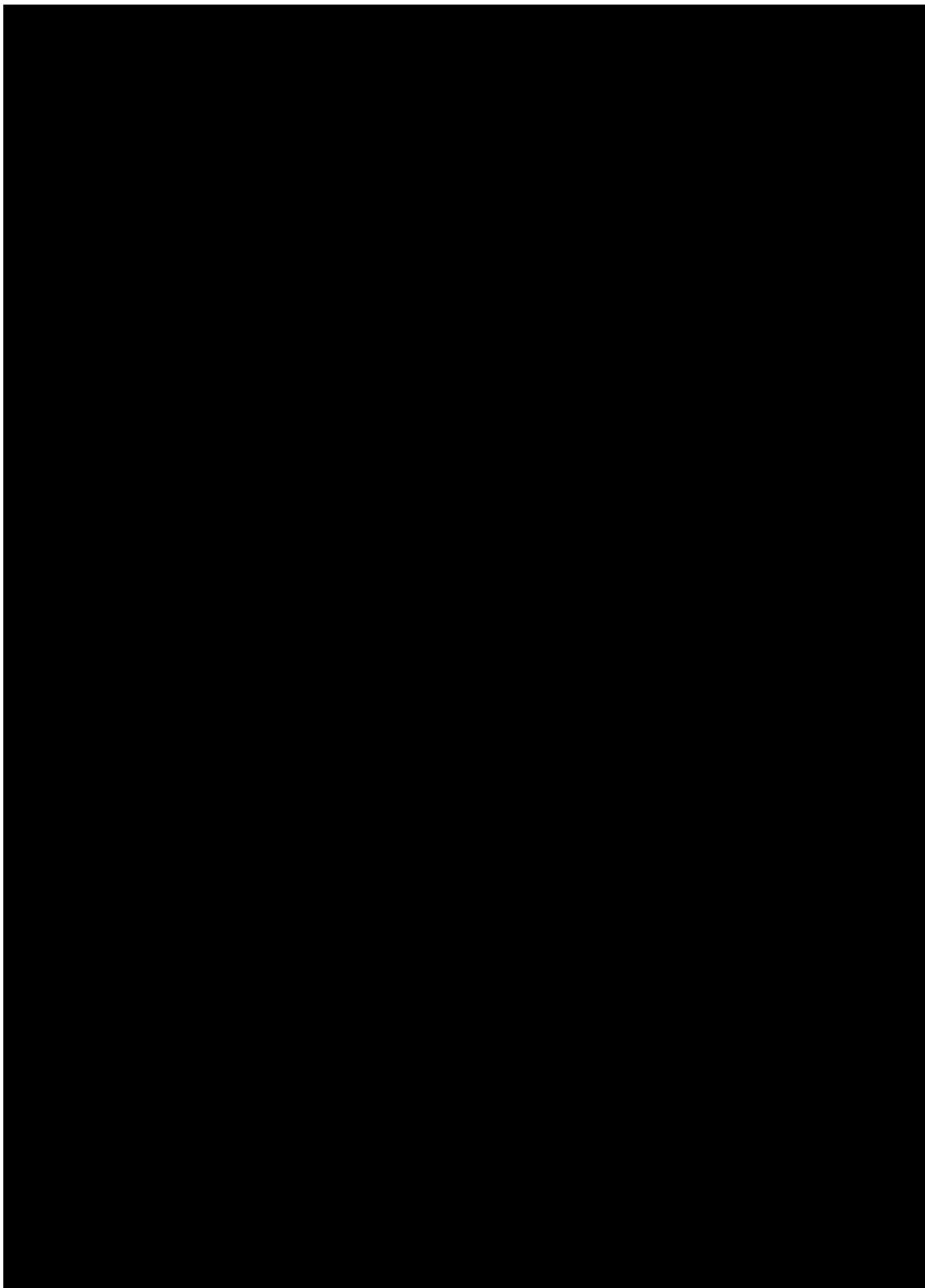


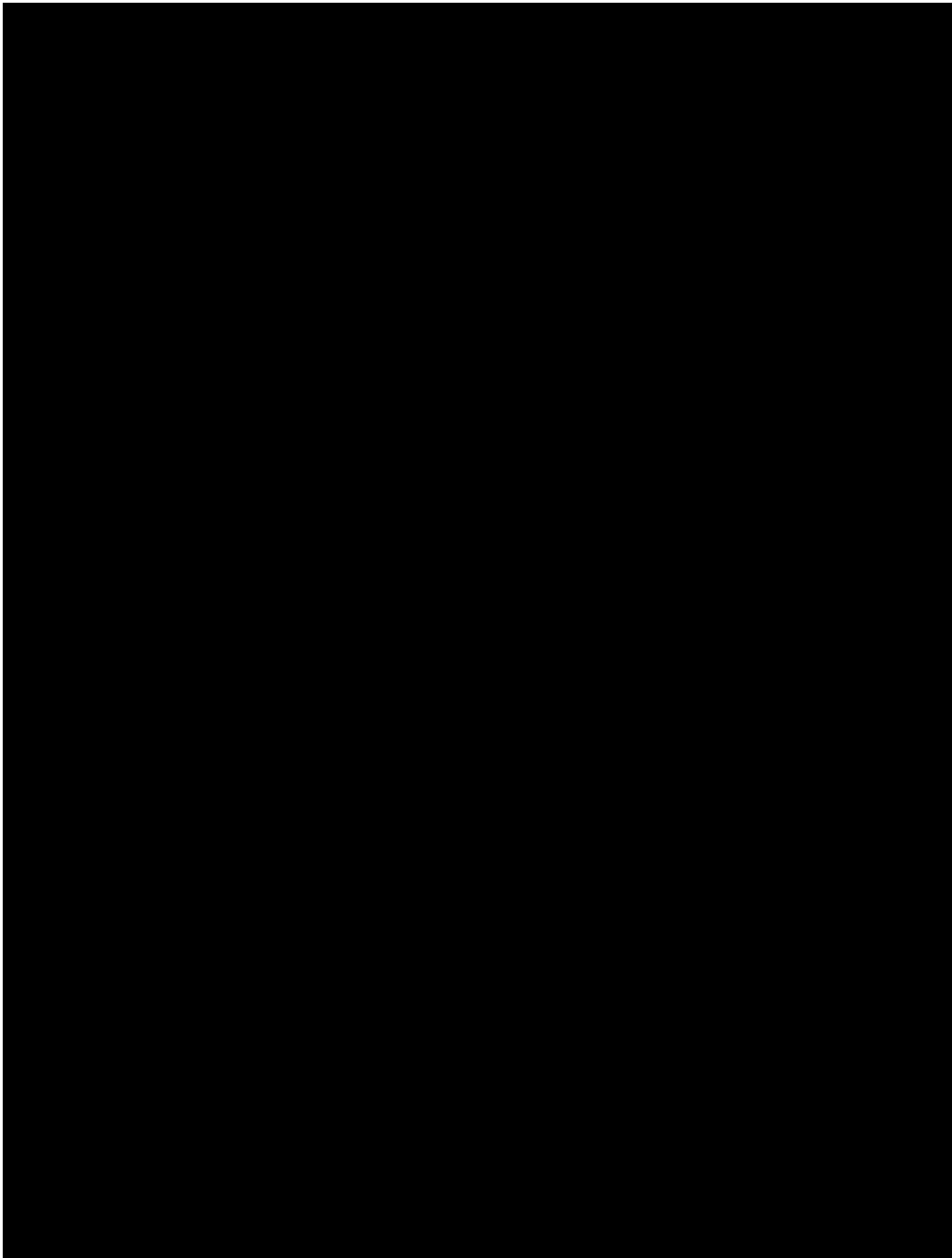


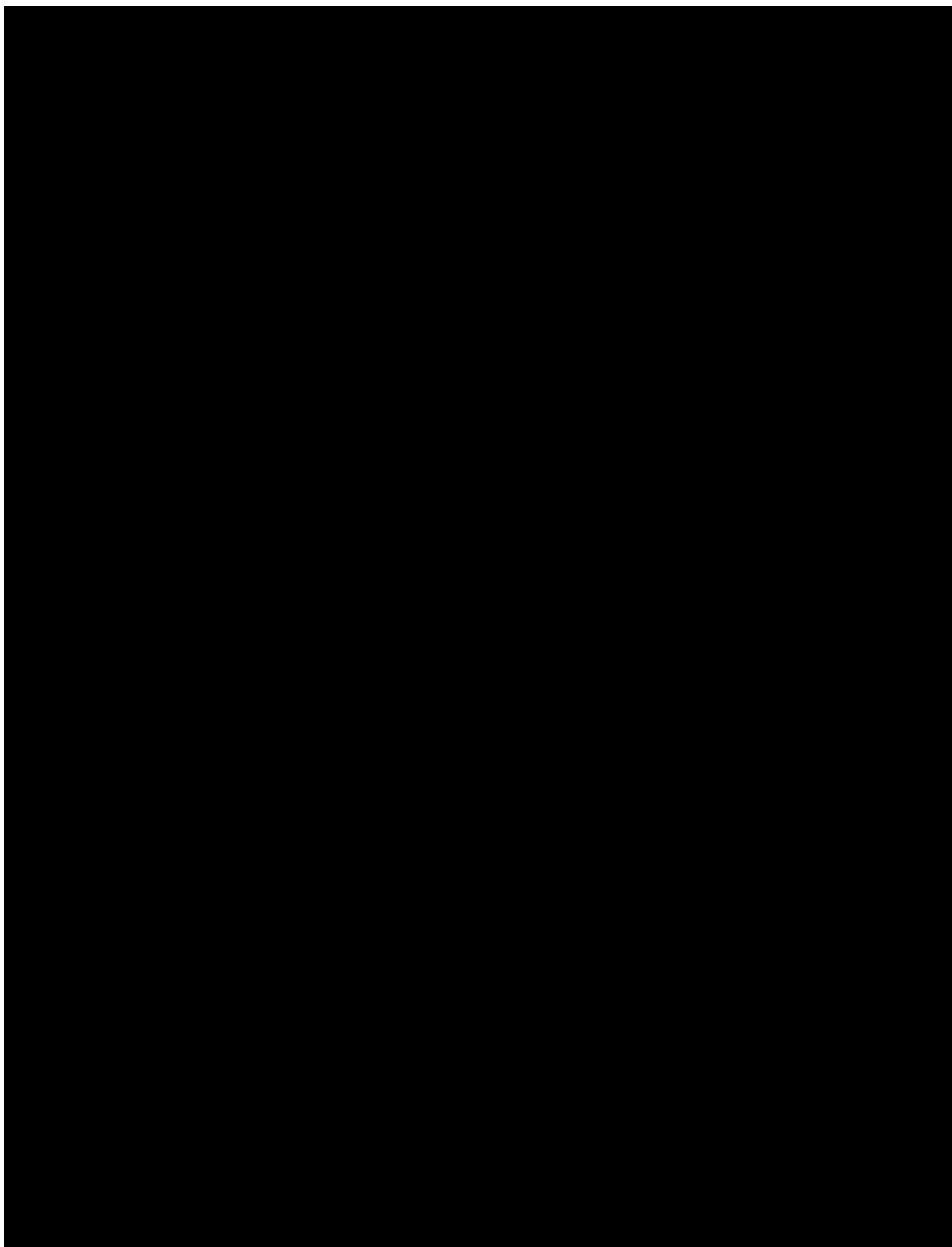


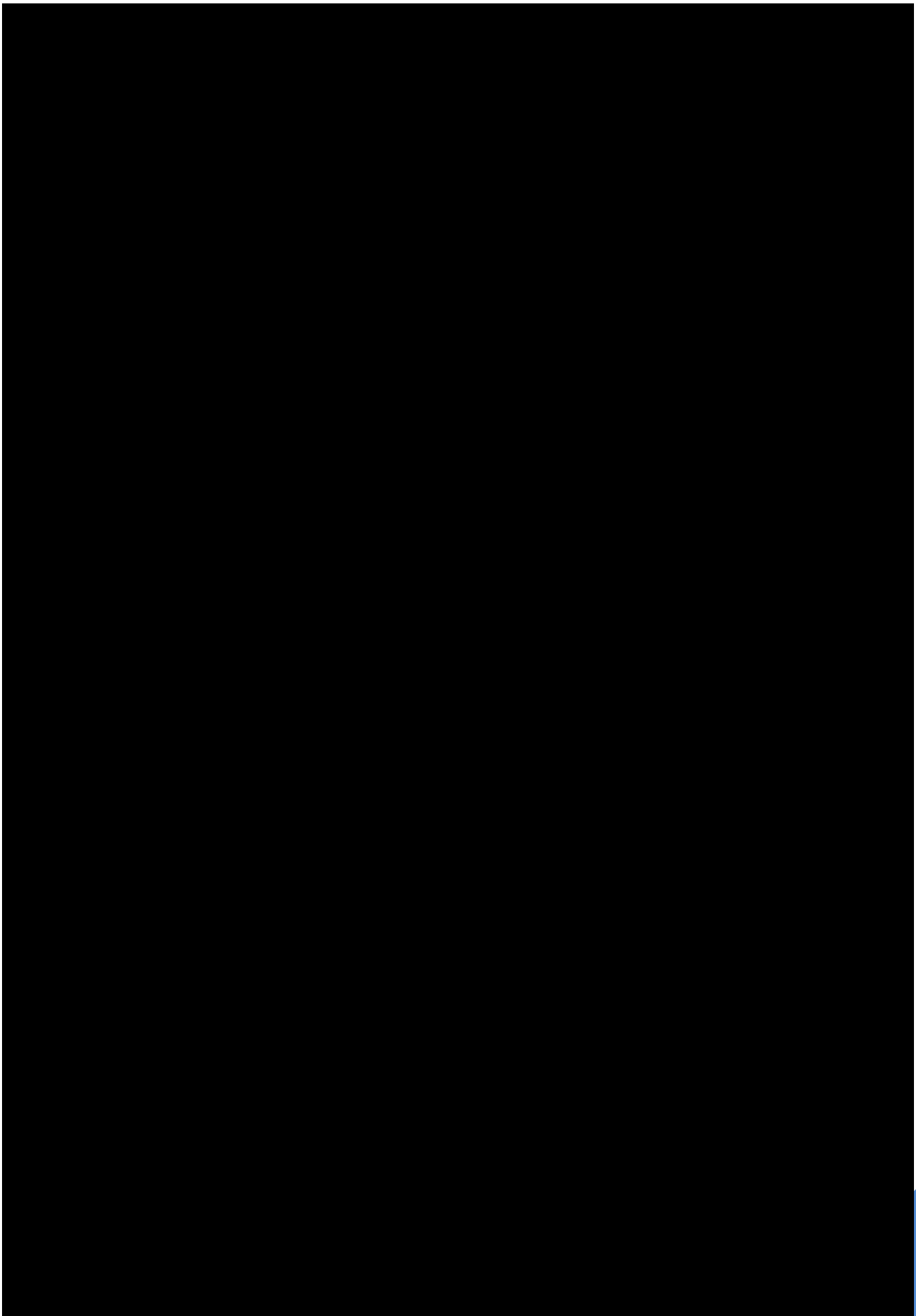


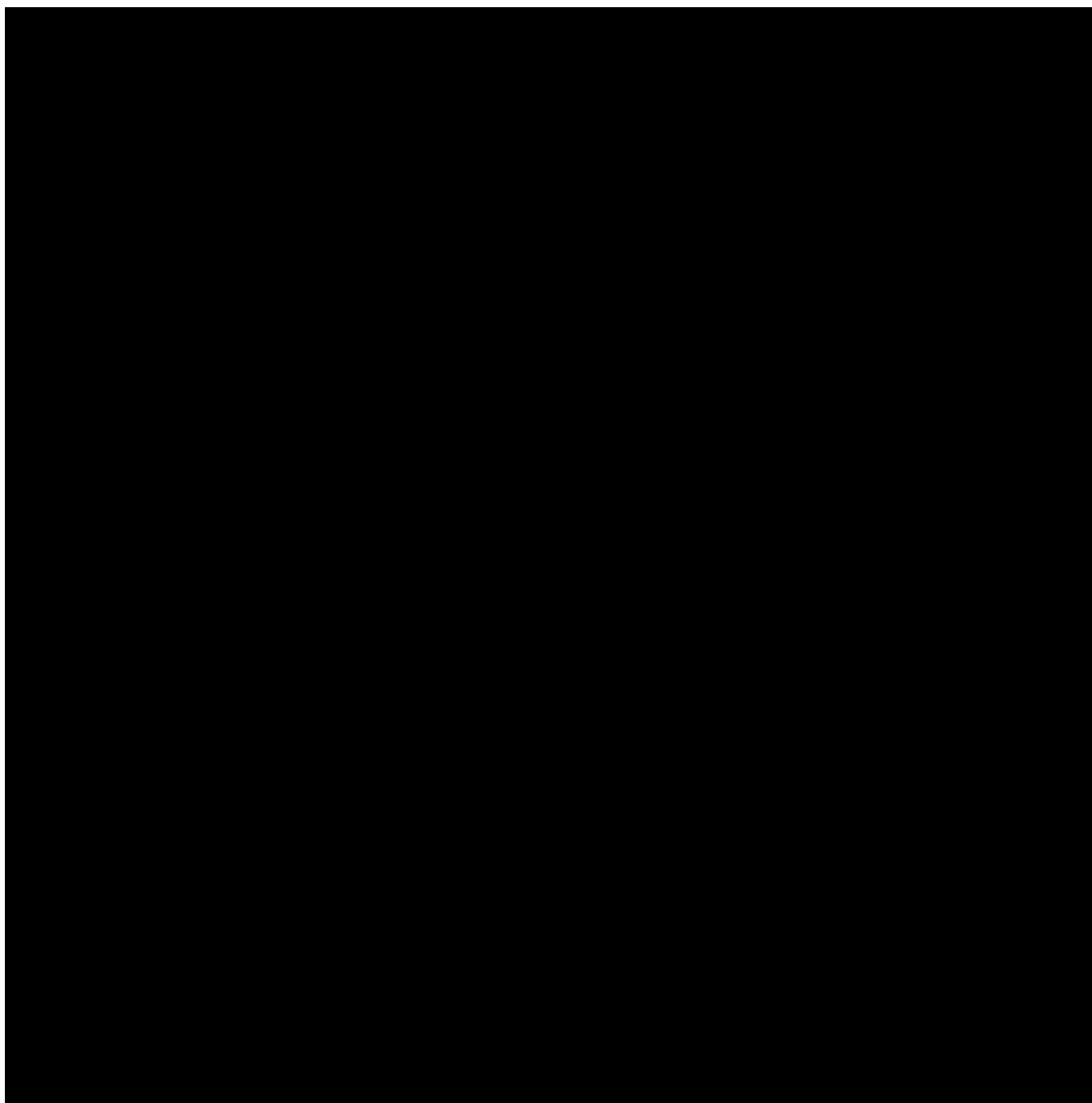


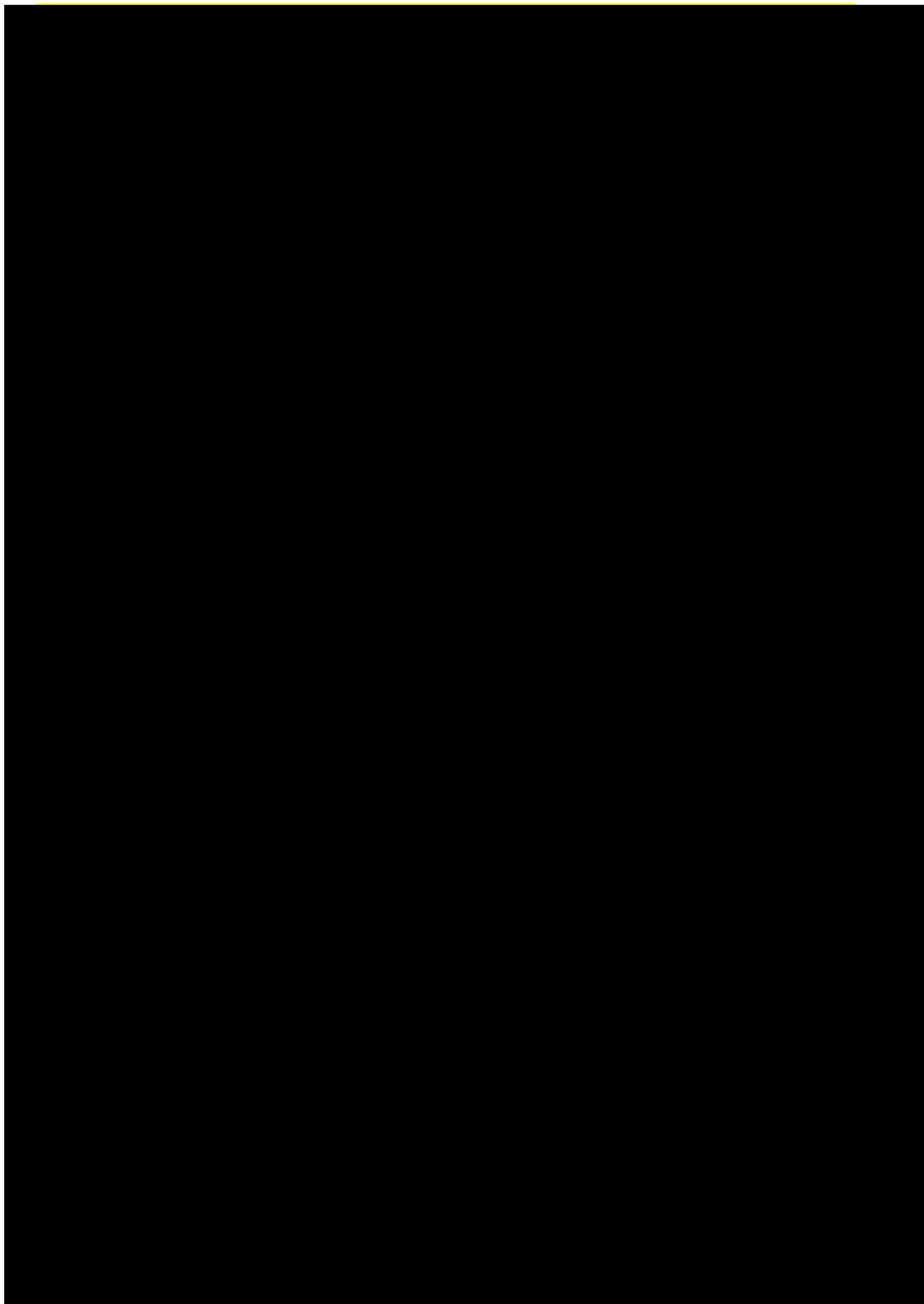


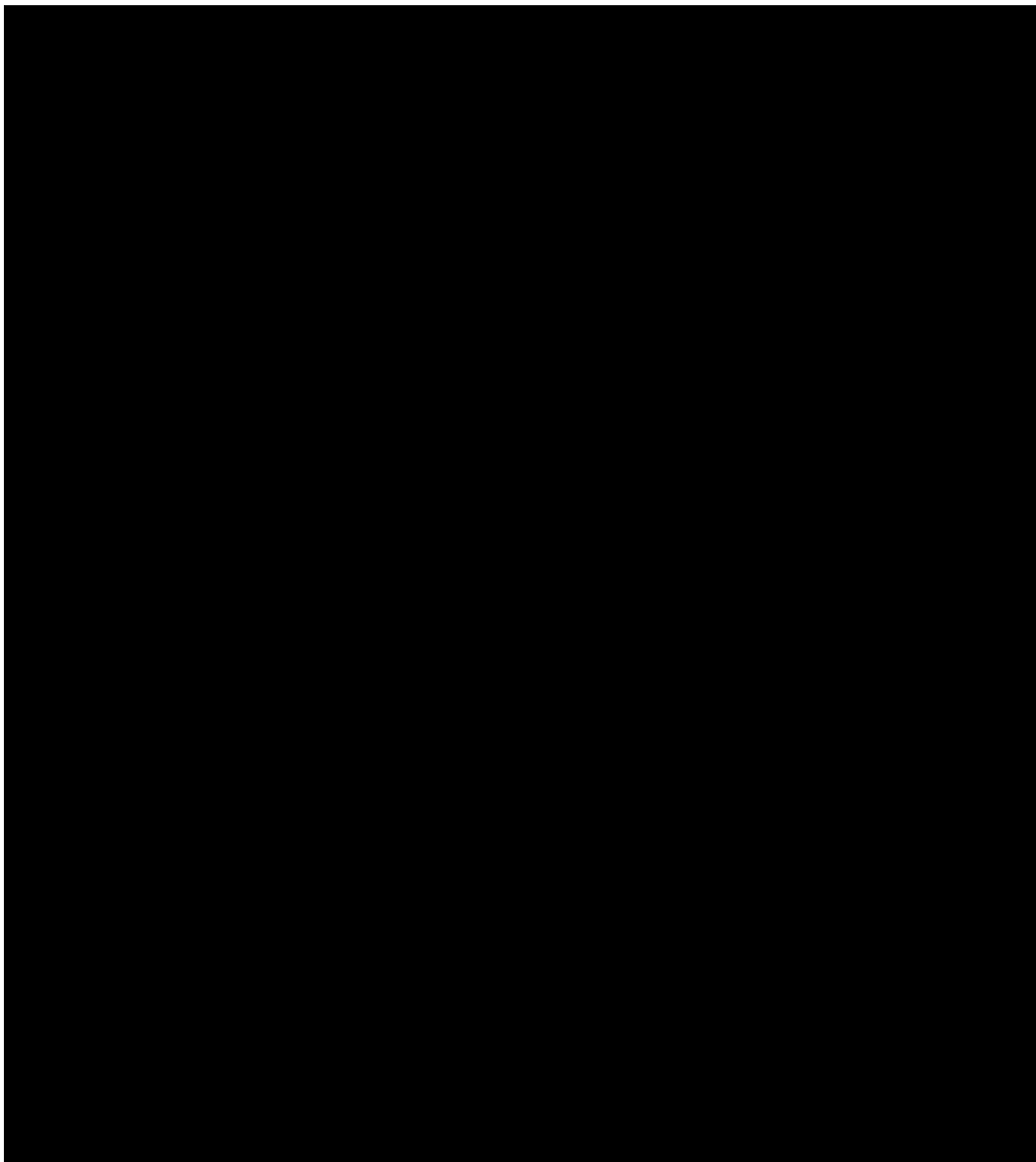


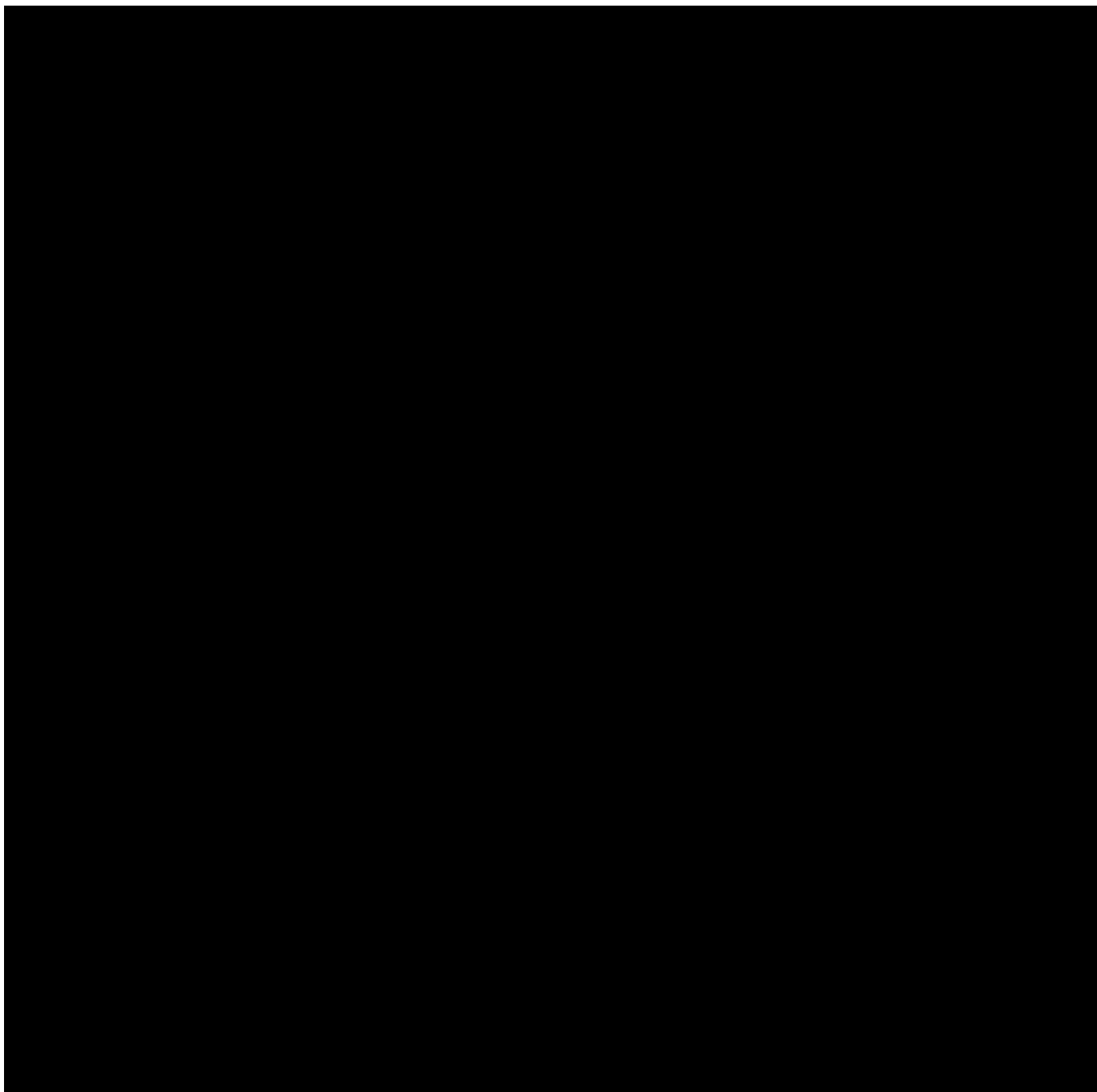


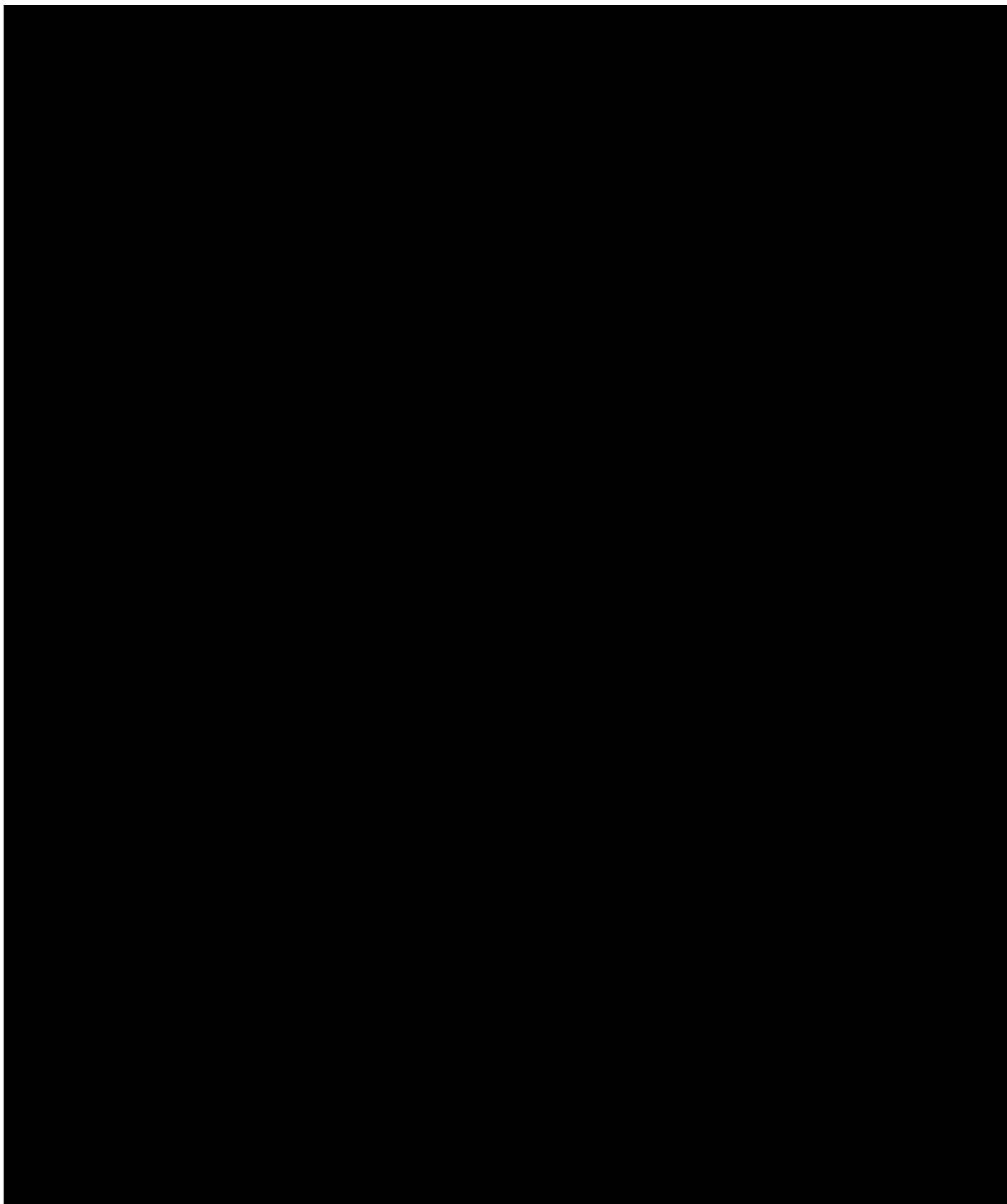












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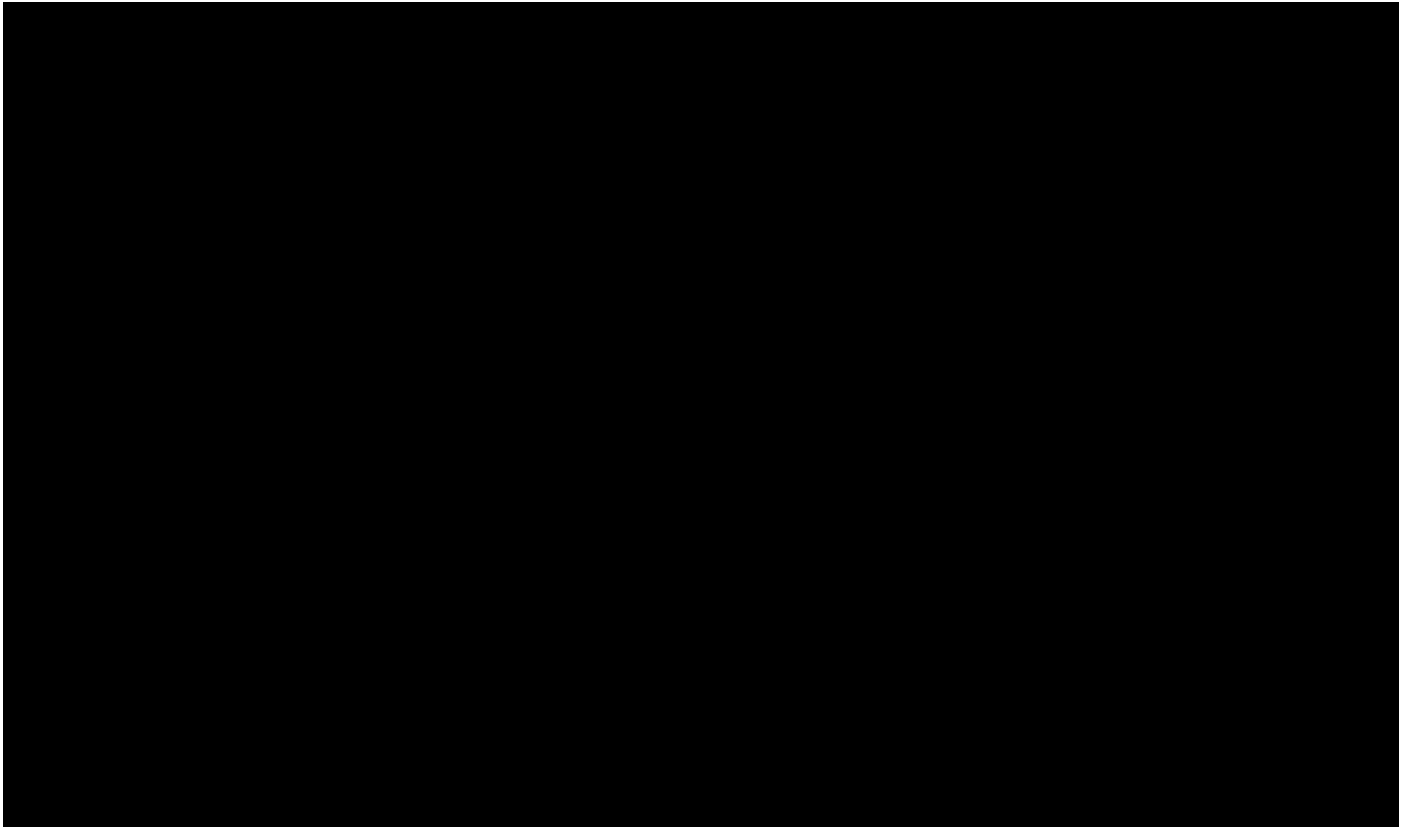
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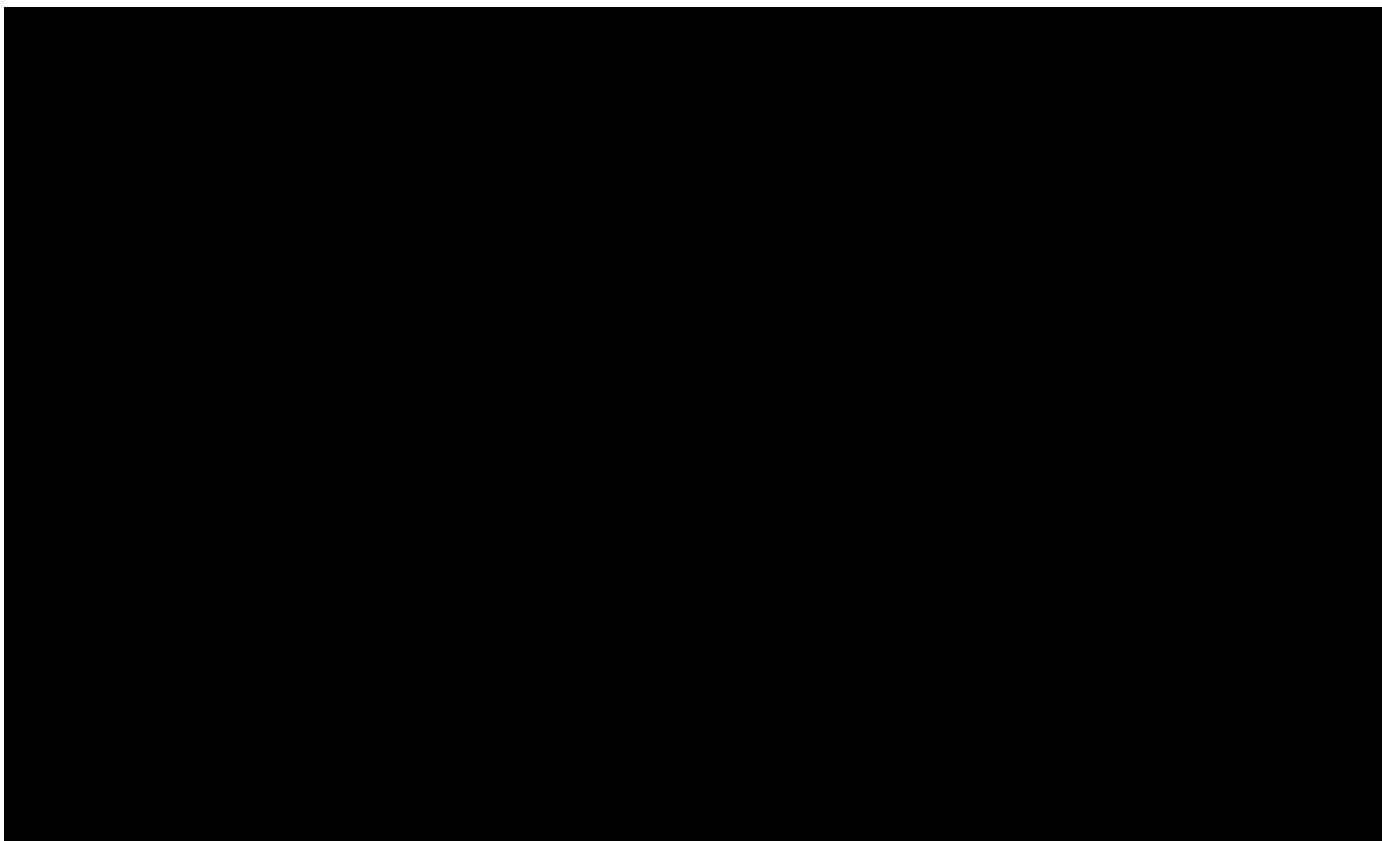
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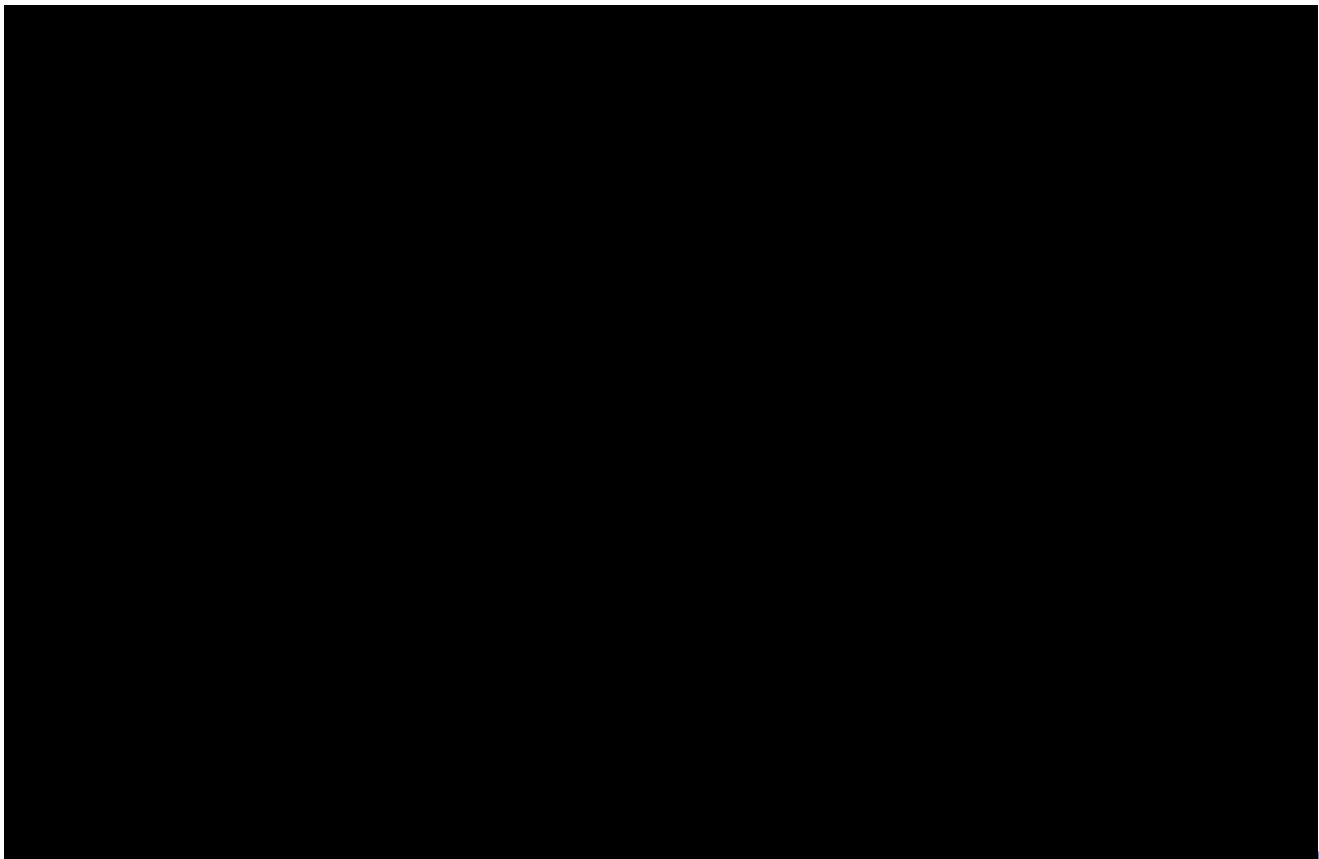
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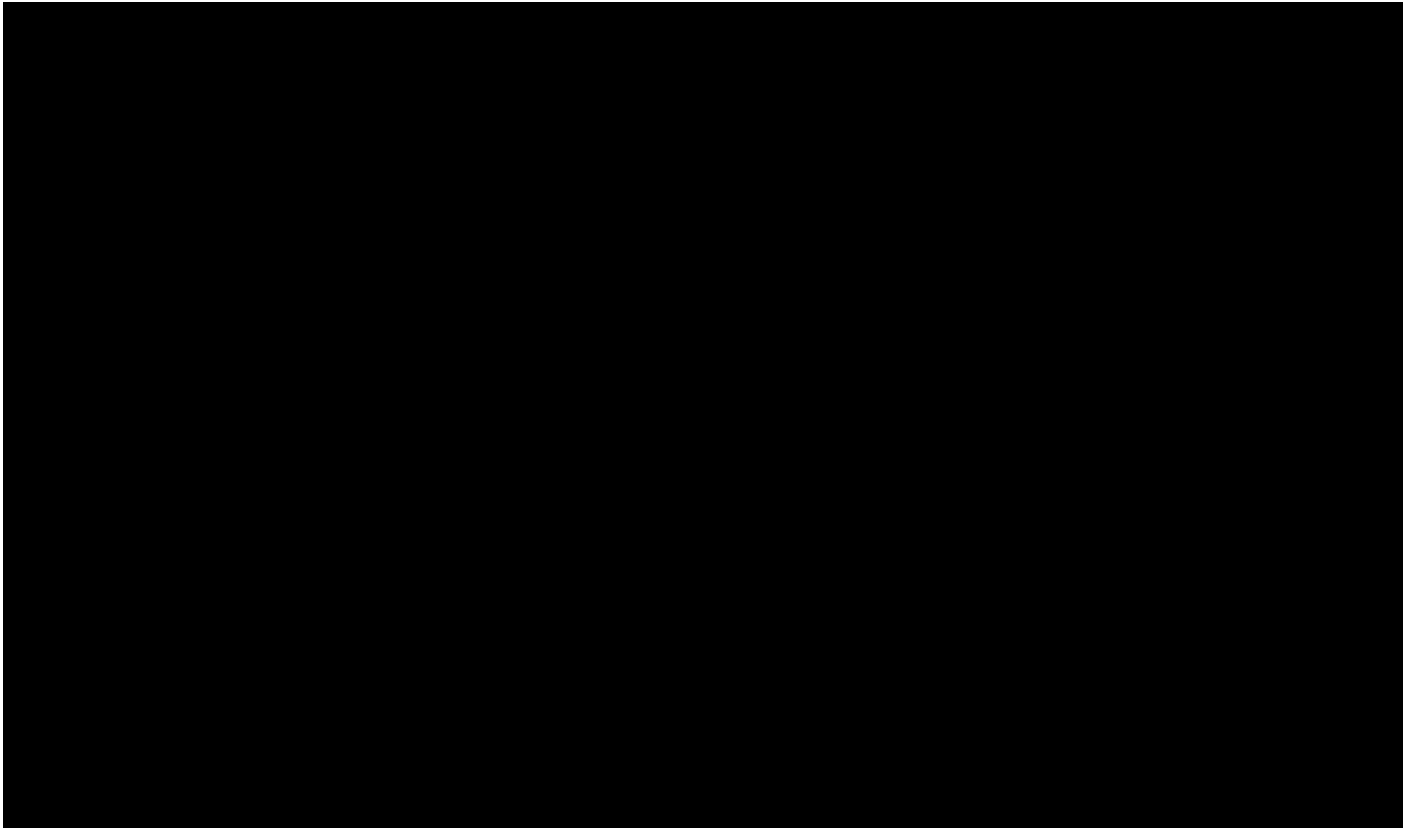
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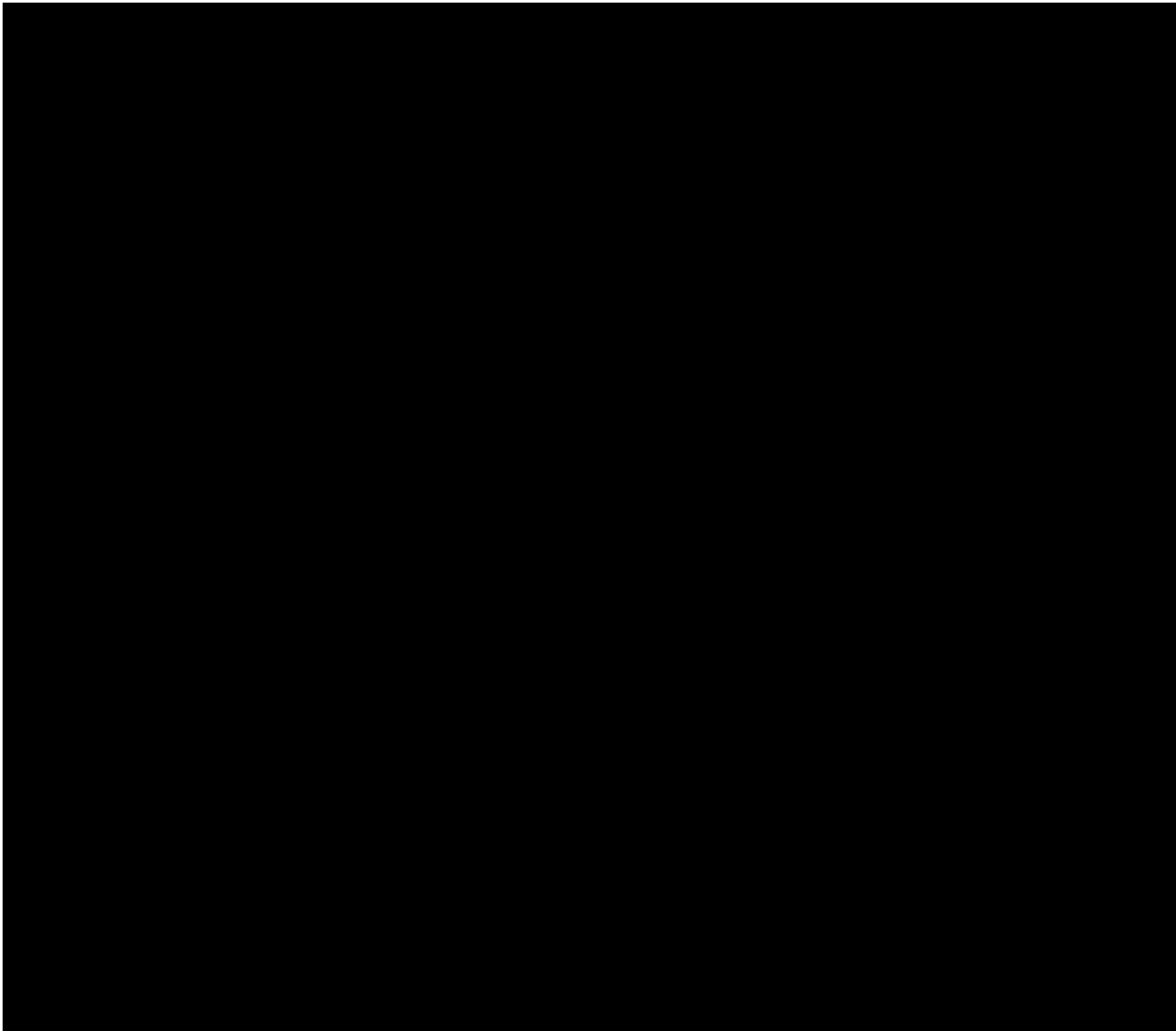
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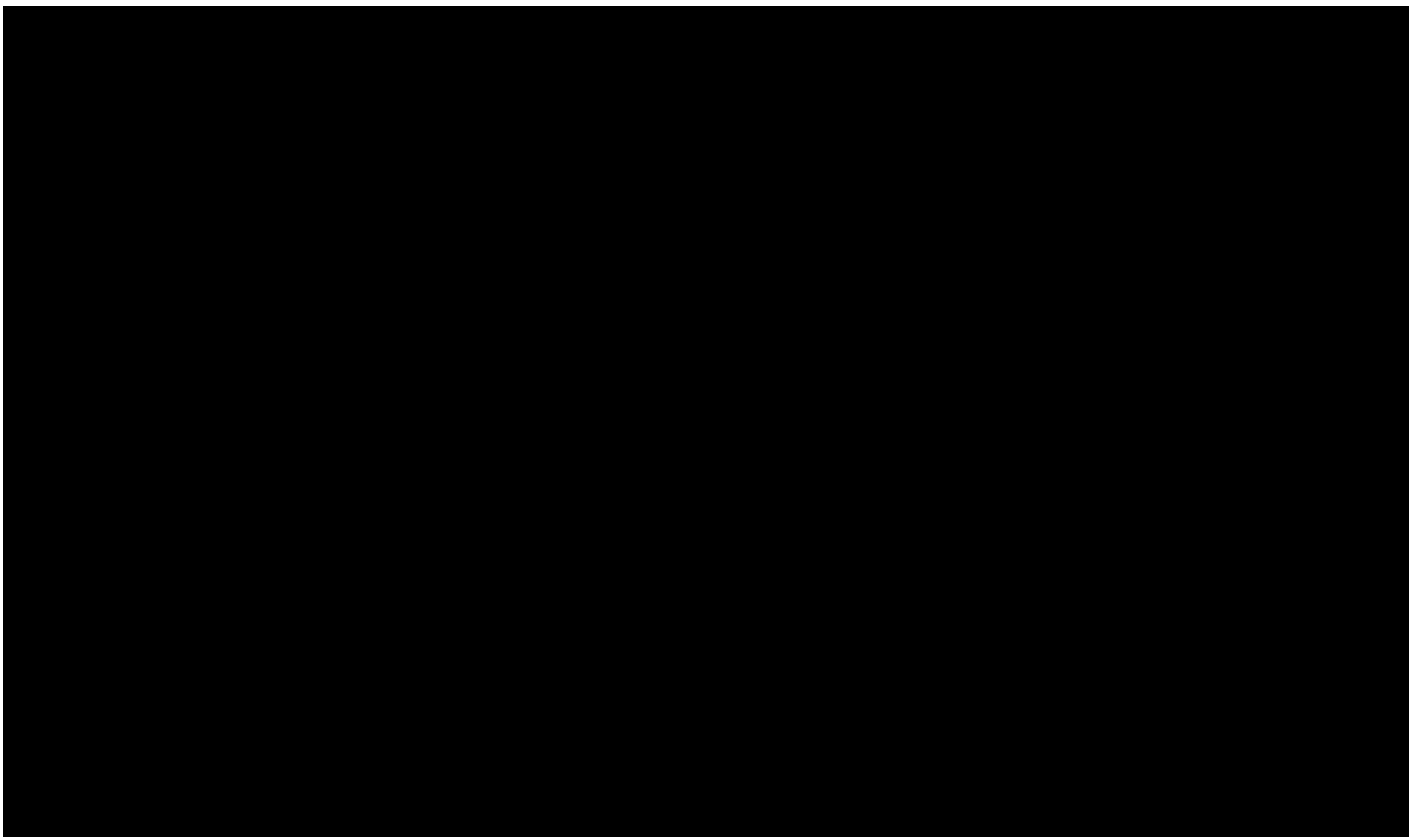
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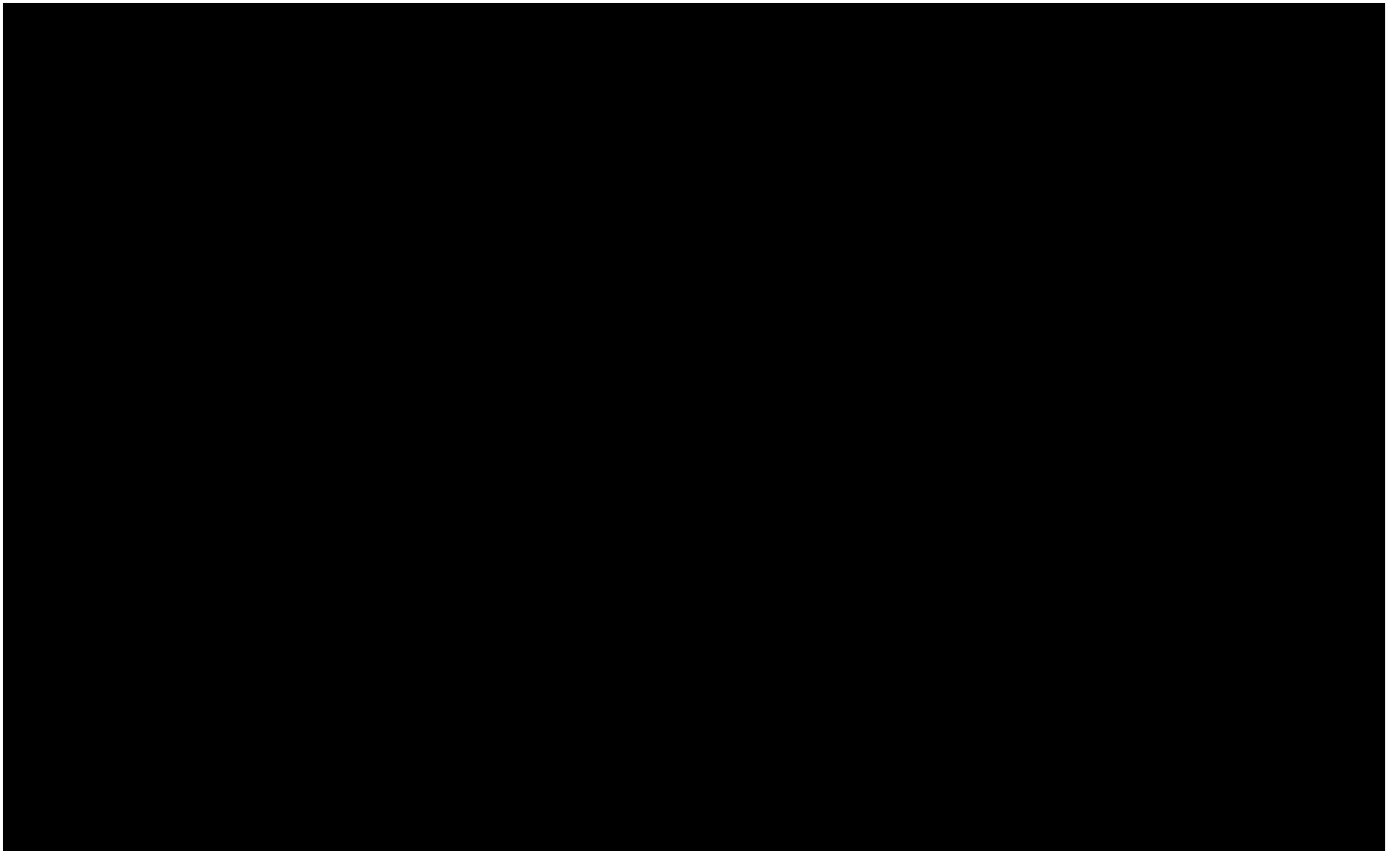
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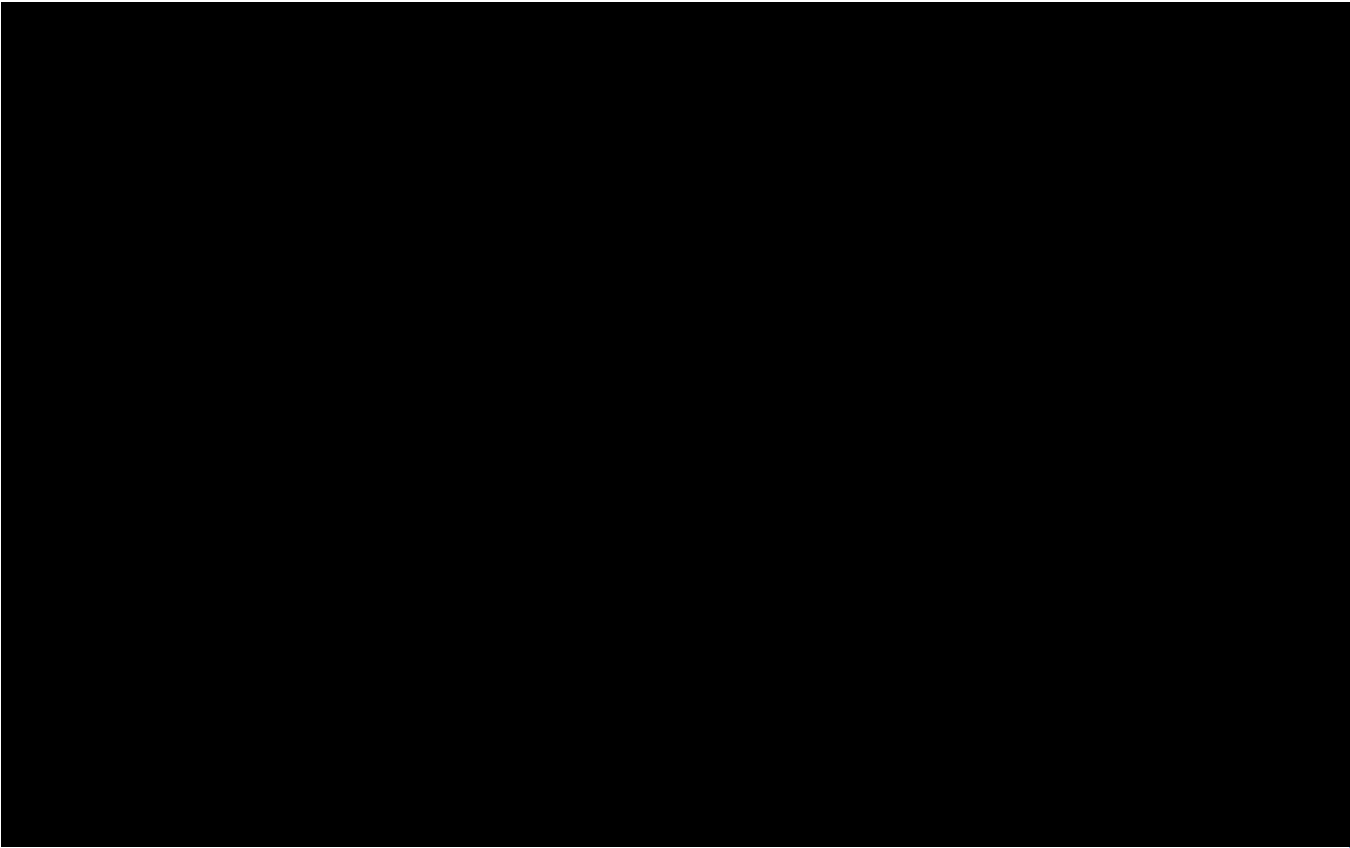
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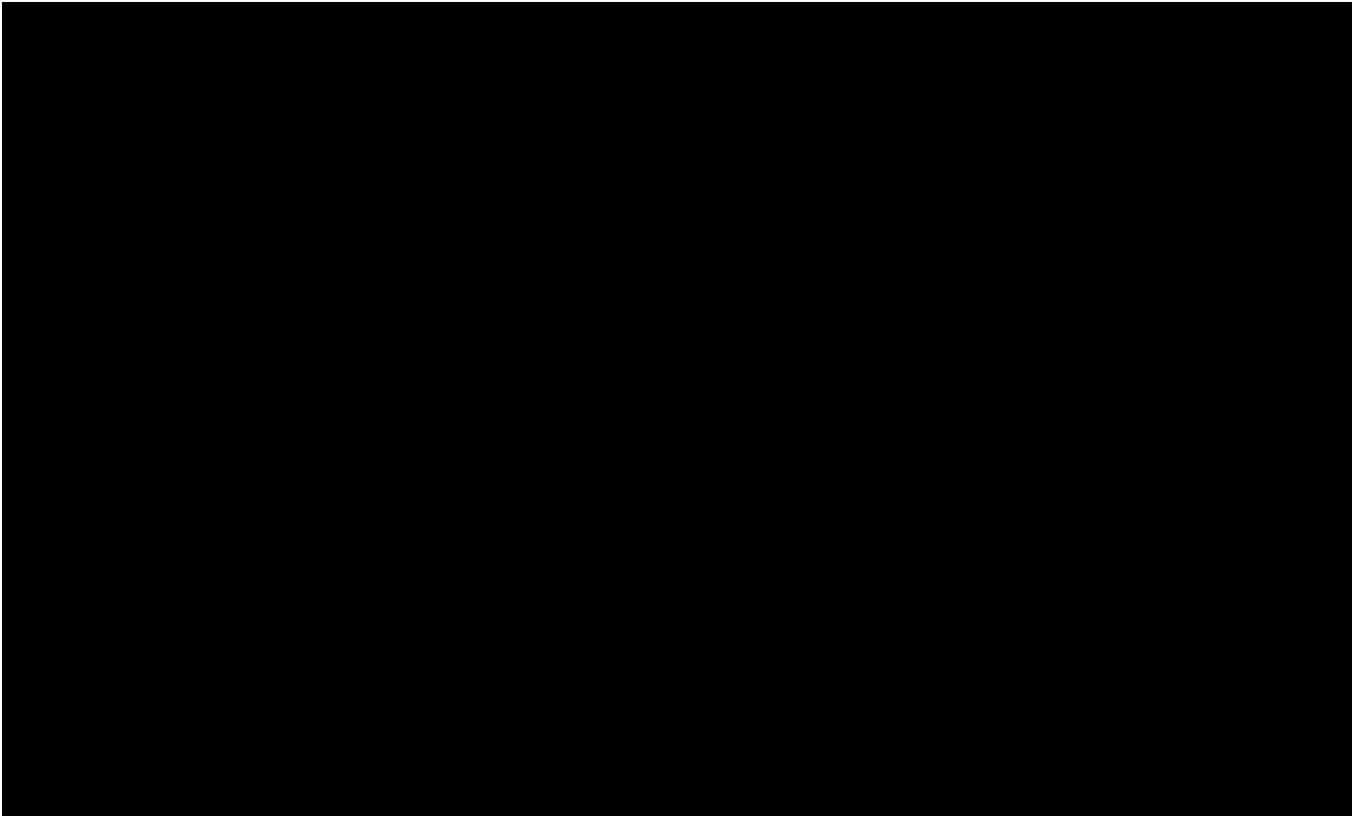
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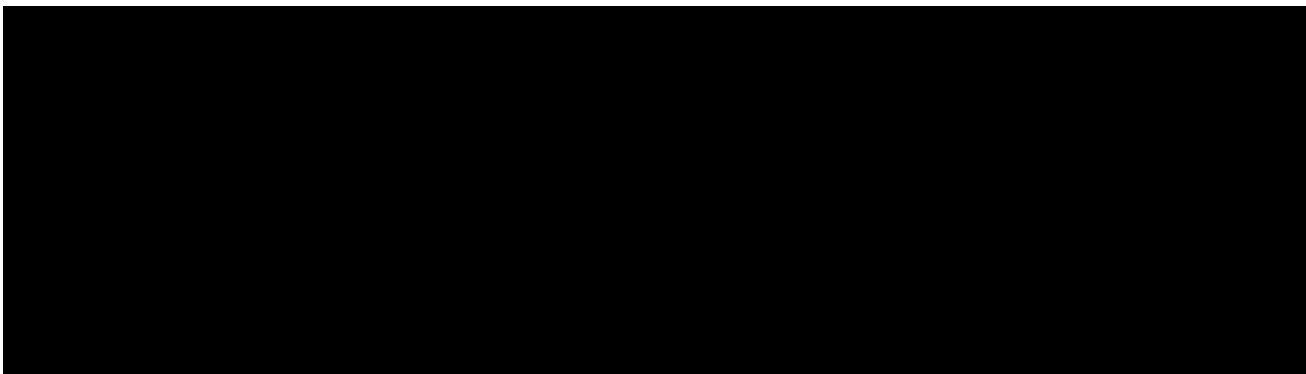
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The table is a complex grid with approximately 10 columns and 20 rows. It is divided into several sections by horizontal lines. The top section contains a few rows with some redacted cells. The middle section is a large block with many rows, where most cells are redacted. There are several rows in this section that are highlighted in light blue. The bottom section contains a few more rows, also with some redactions. The overall structure suggests a detailed data table, possibly a clinical trial summary or a product specification sheet, but the specific data is obscured.

The table contains multiple rows of data, with columns separated by vertical lines. The content is almost entirely obscured by black redaction bars. The table structure is visible through the alternating light blue and white background rows.

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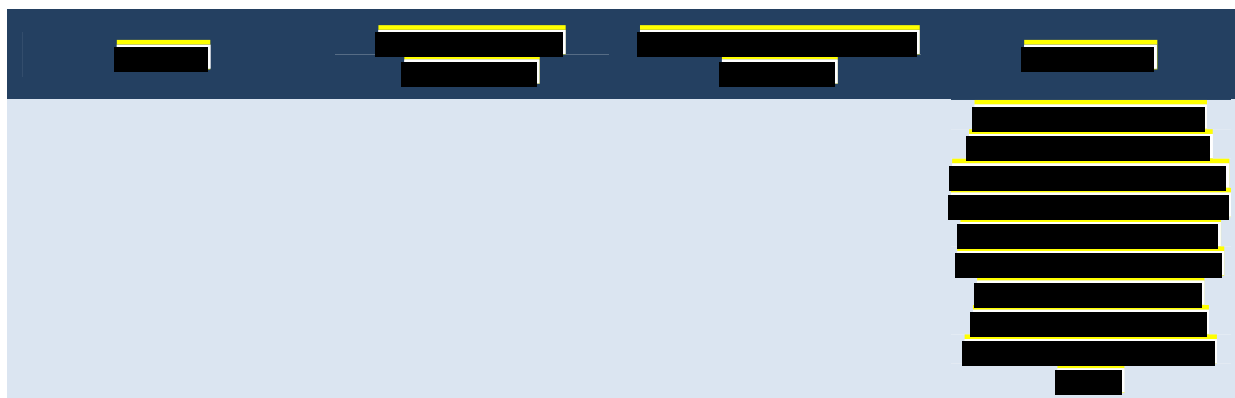
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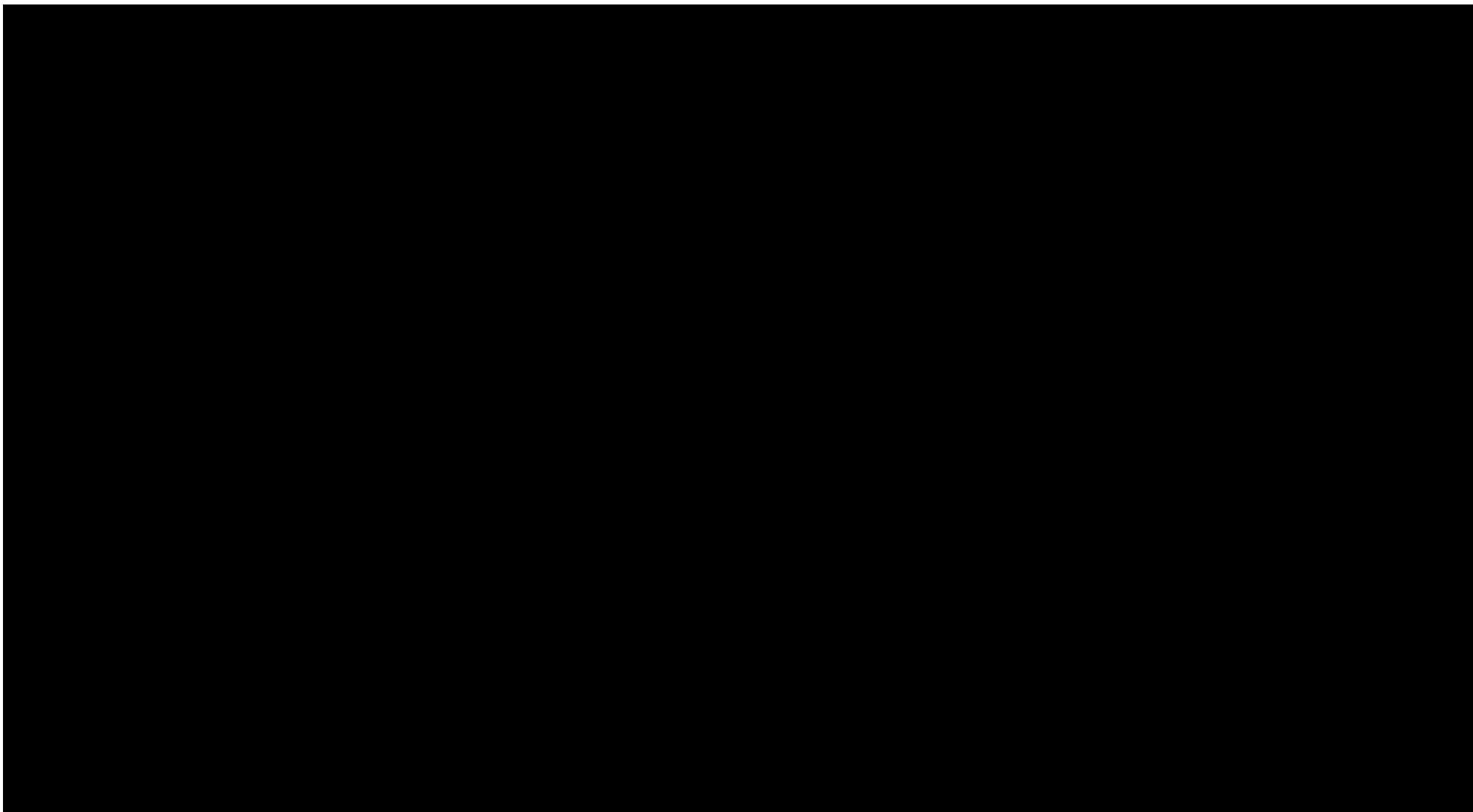
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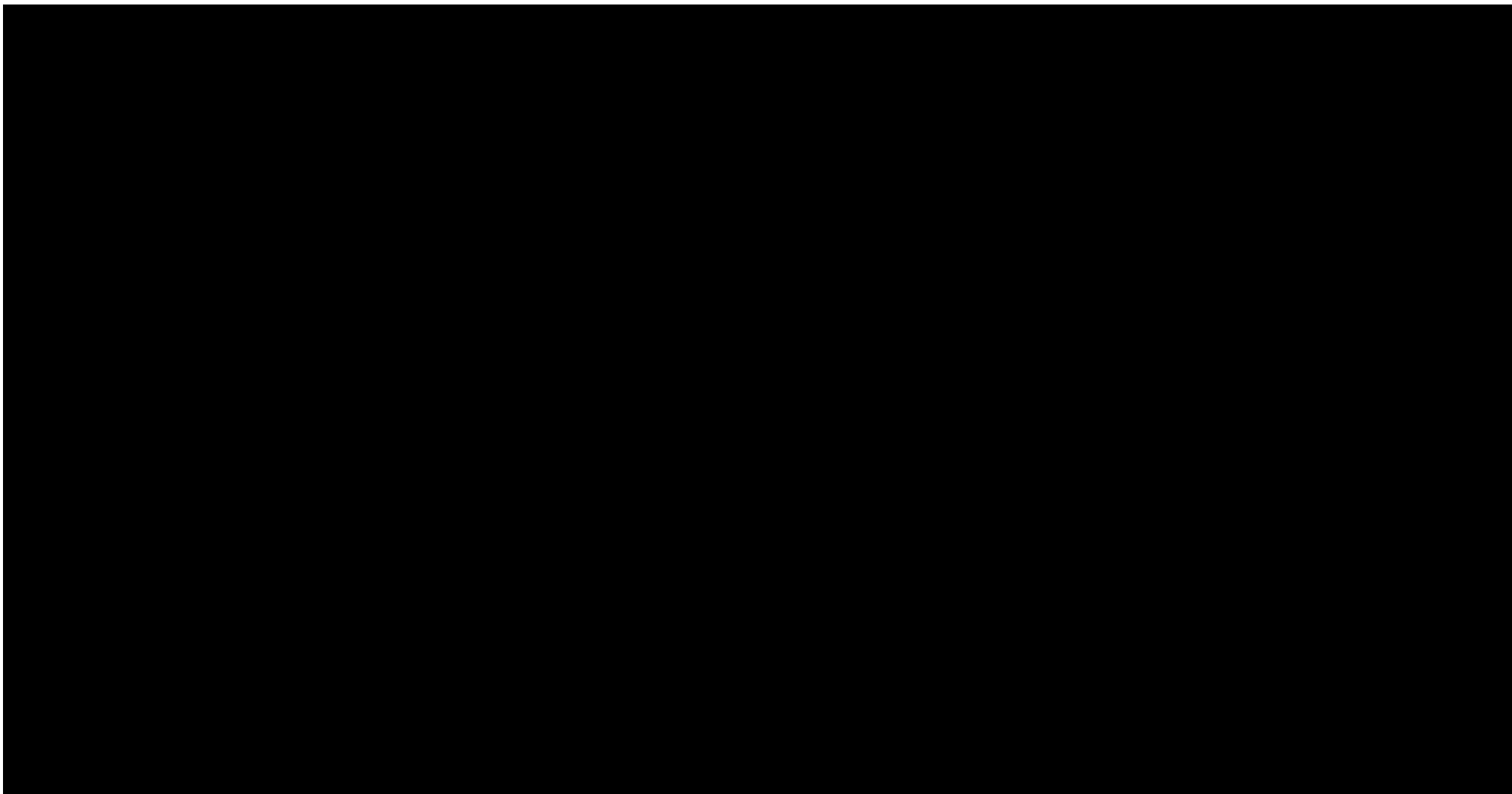
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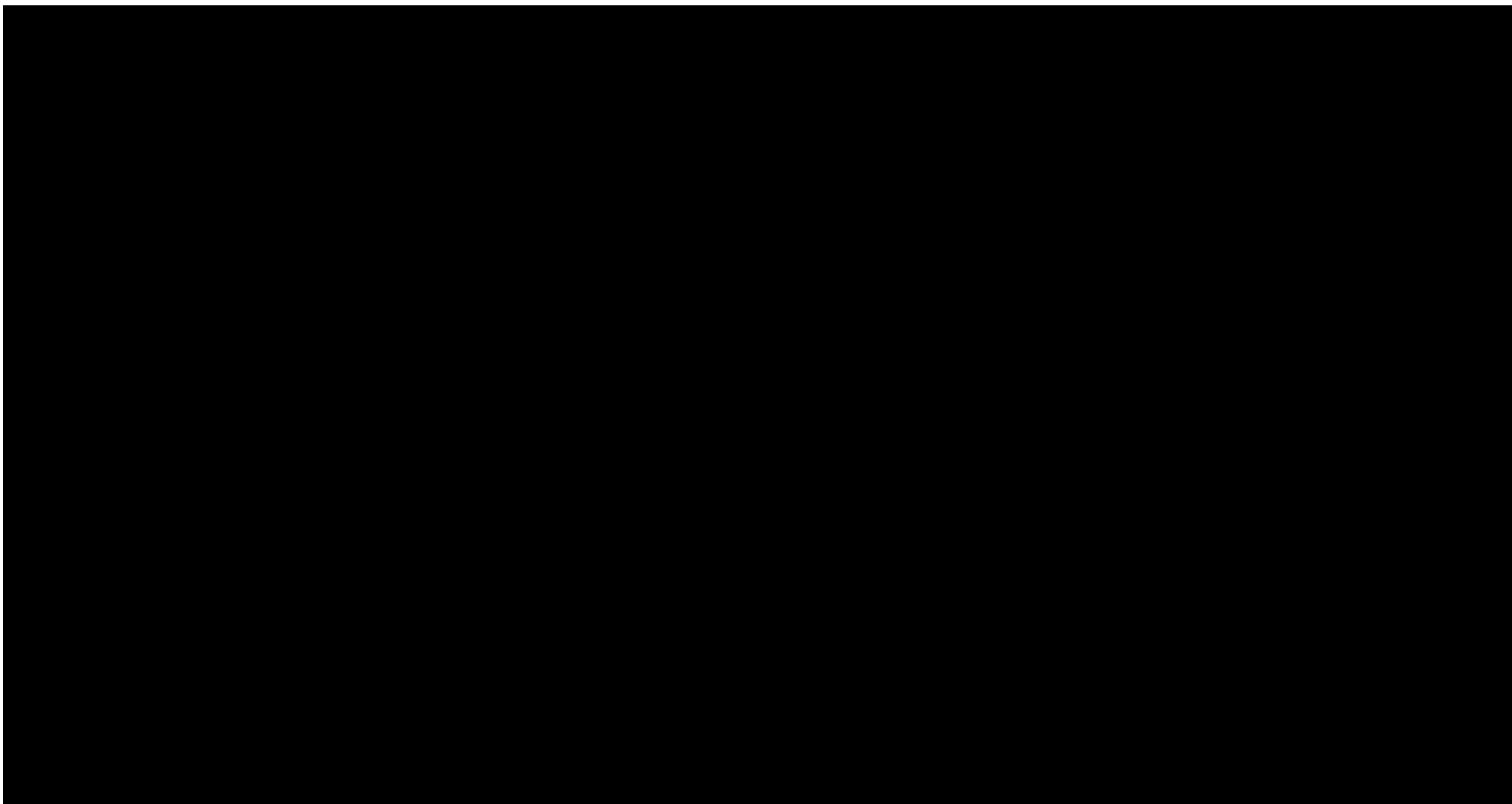
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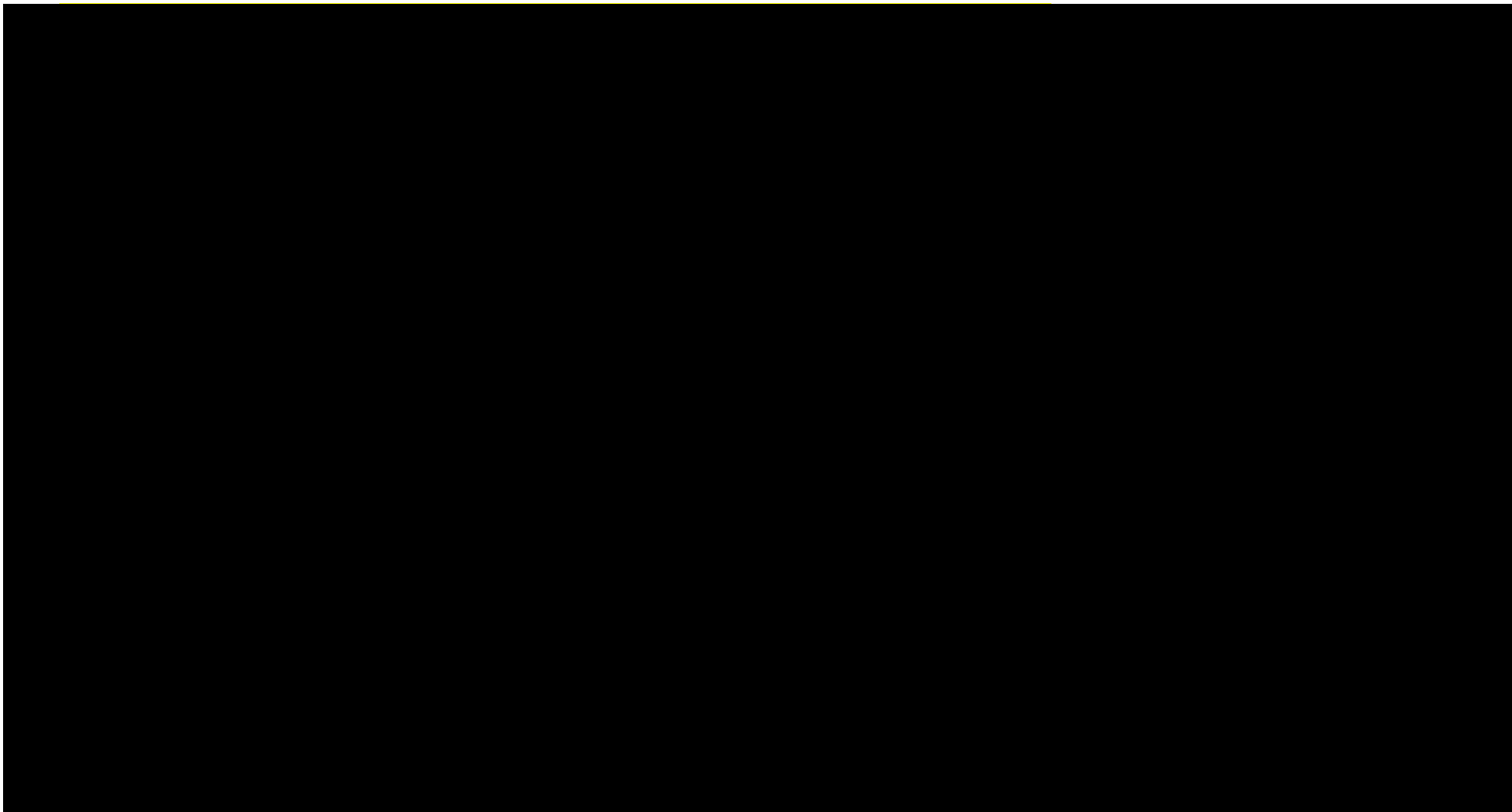
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Table with redacted content (blacked out text).

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The table consists of a dark blue header row and approximately 12 light blue body rows. Each row contains several columns of redacted text, represented by black bars of varying lengths. The redaction covers almost all text within the table's grid.

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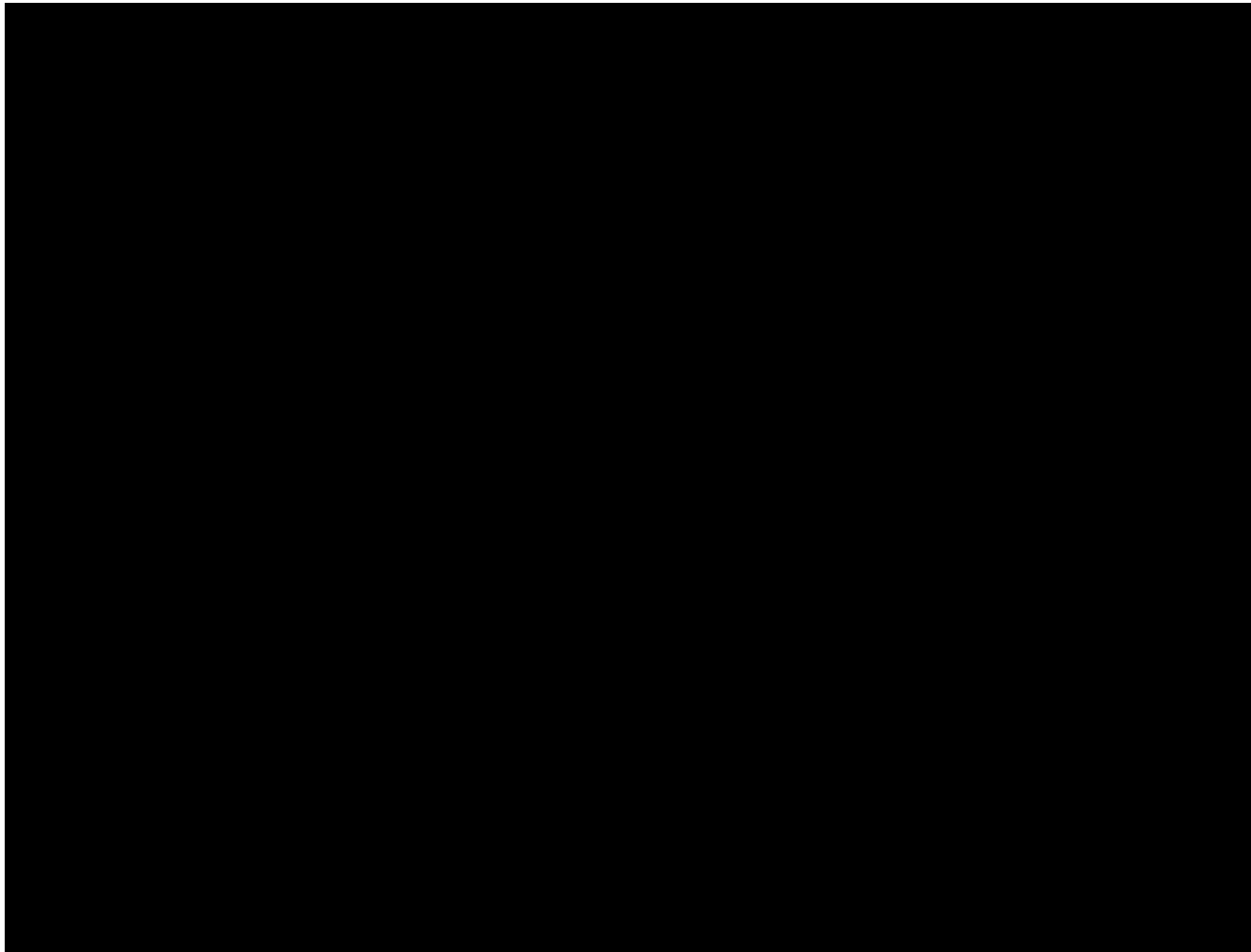
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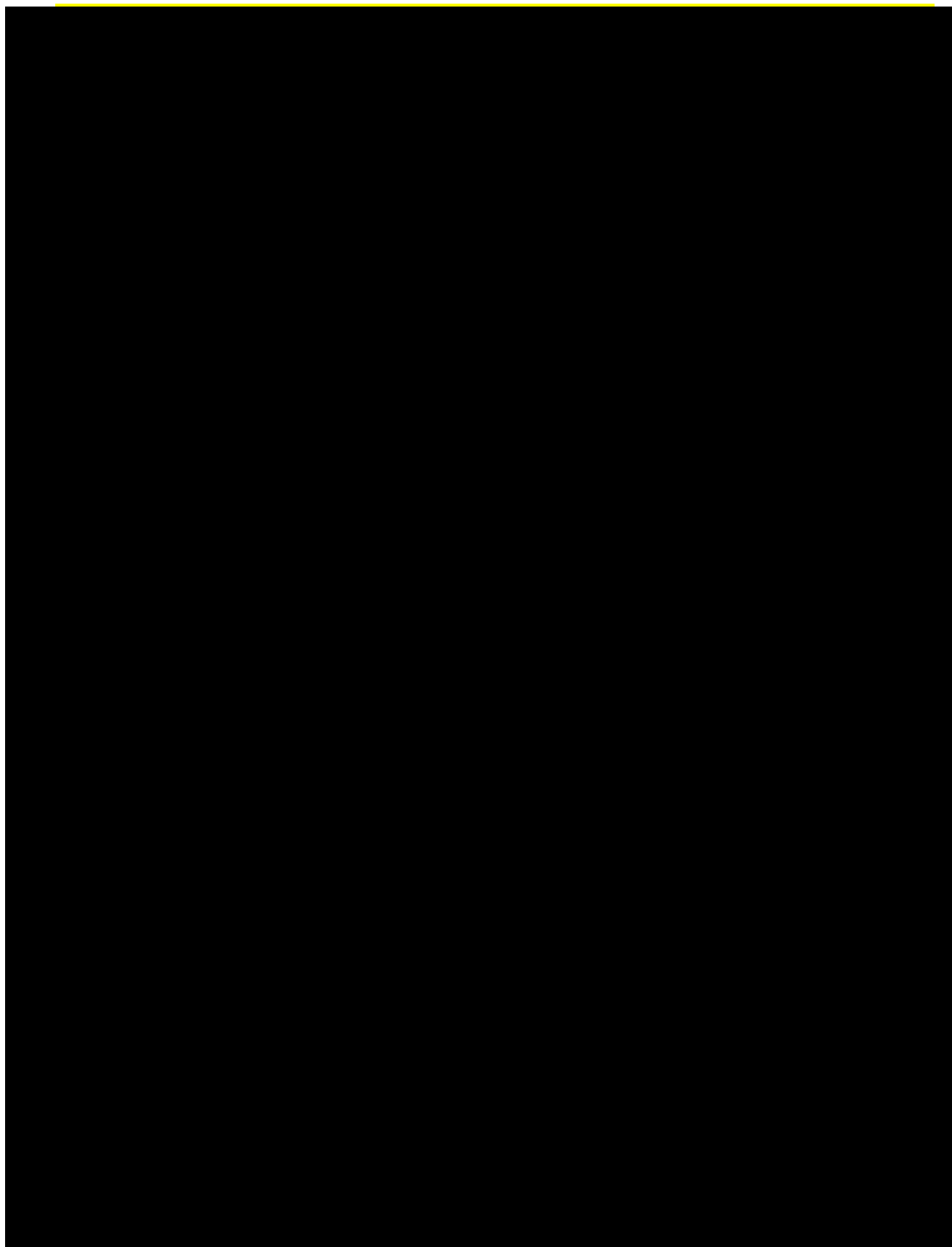
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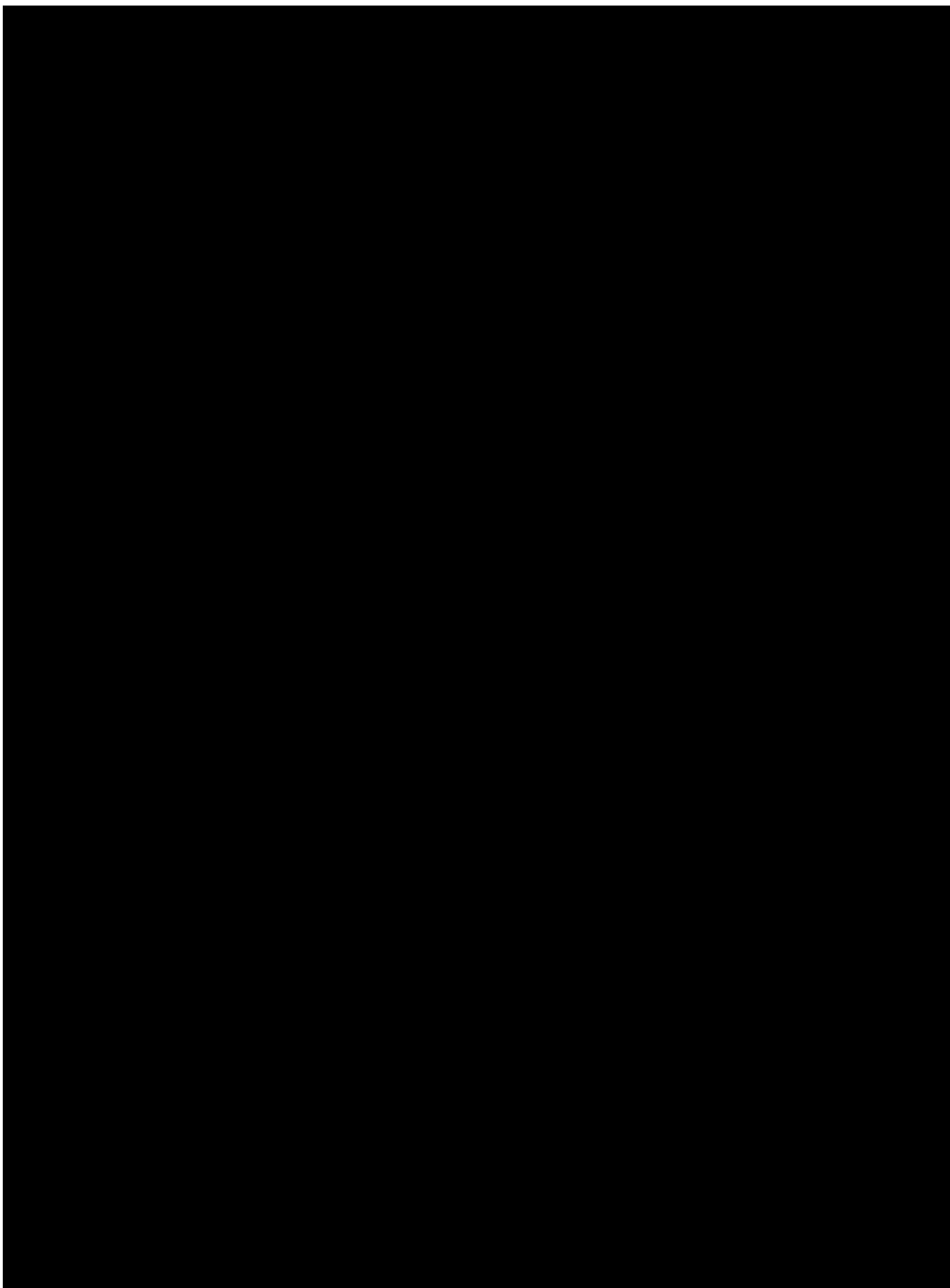
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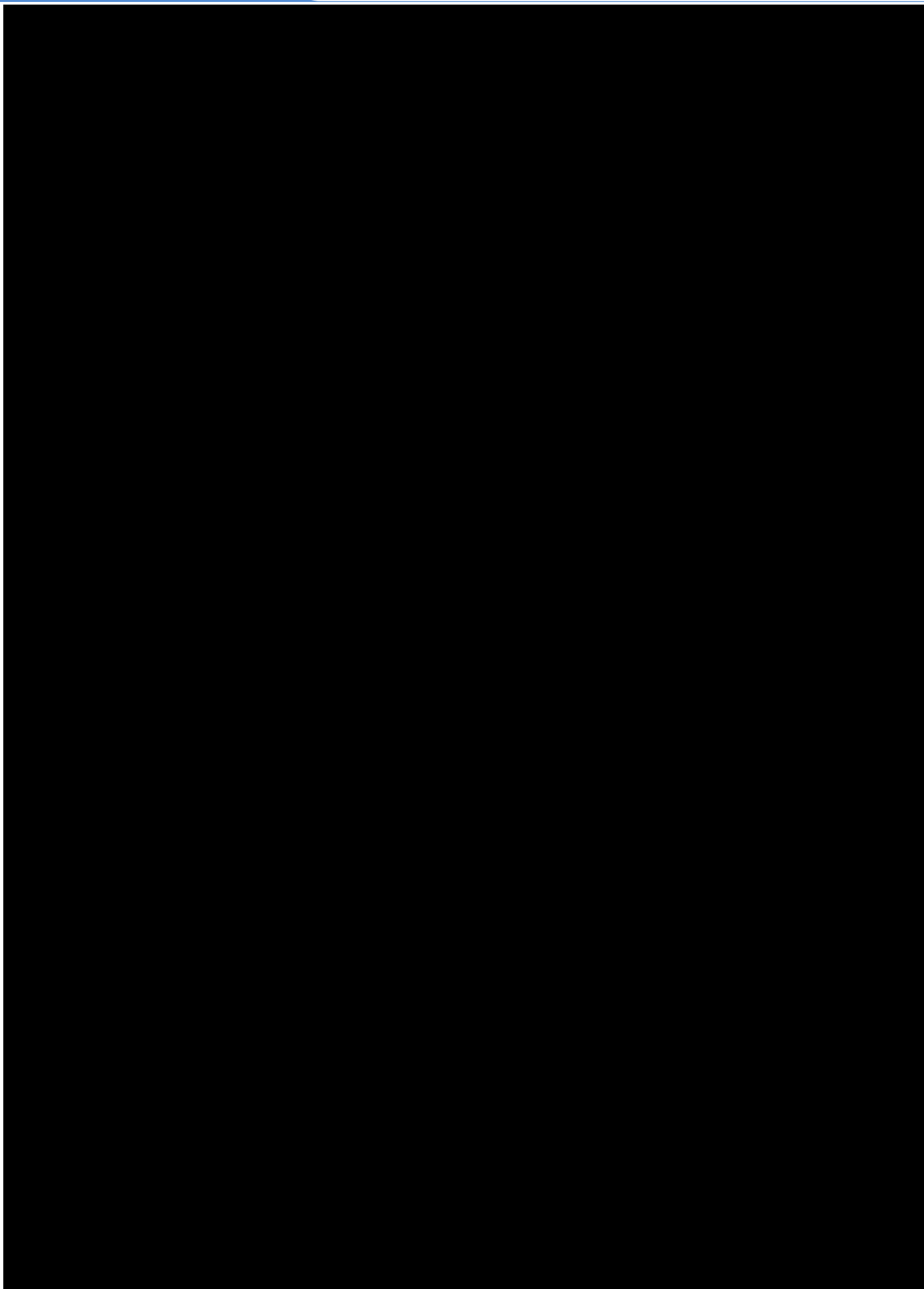
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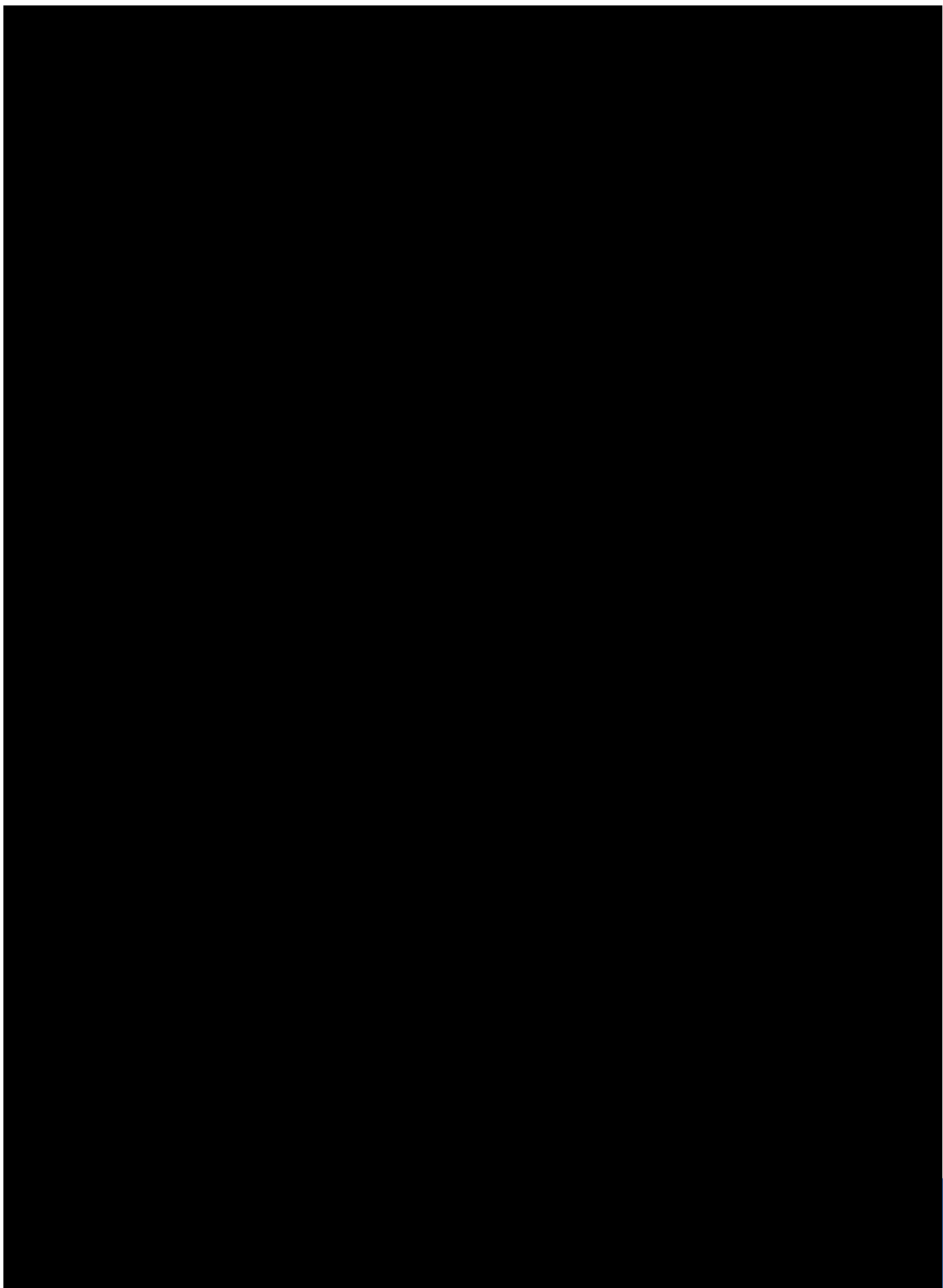
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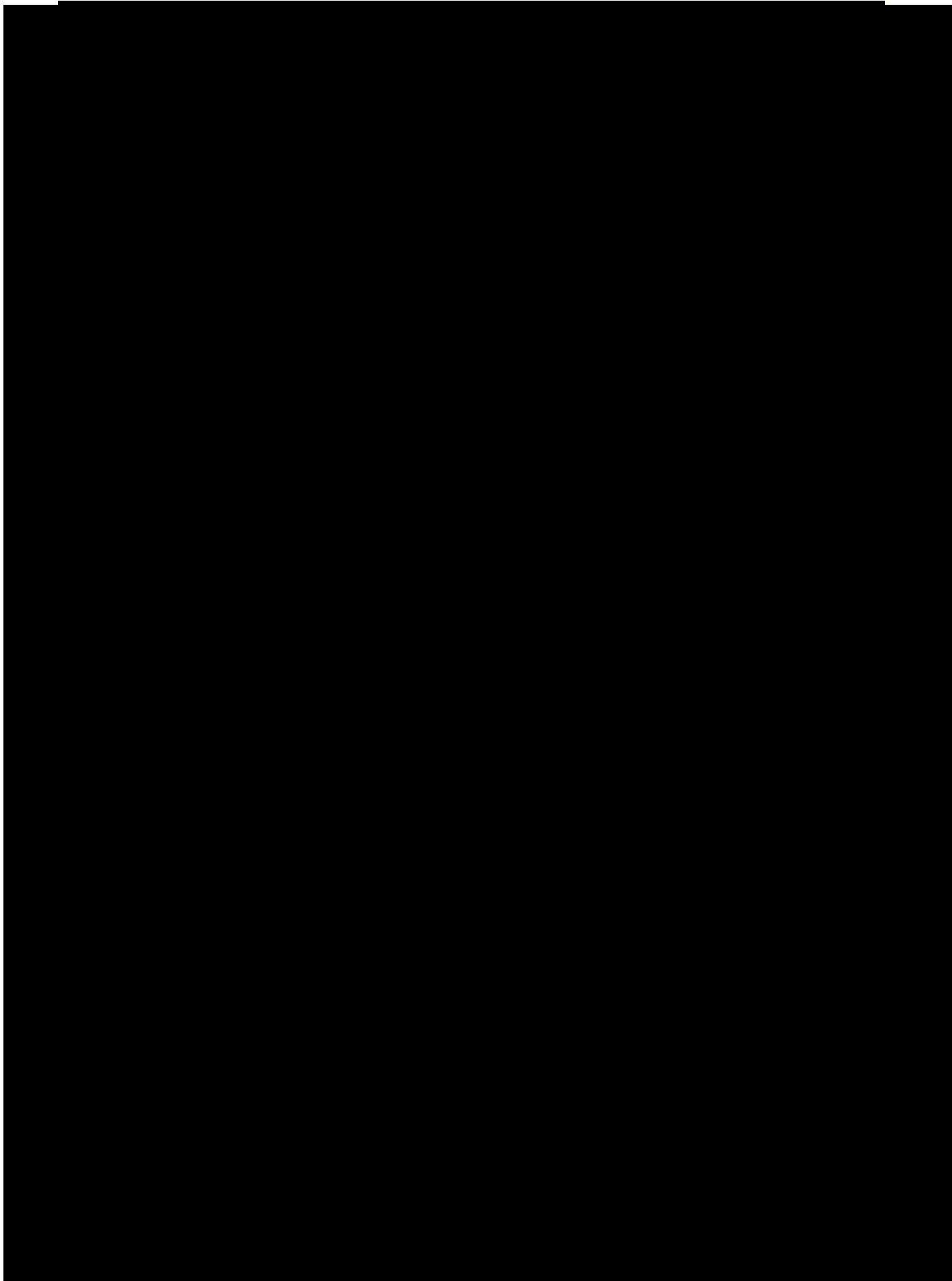
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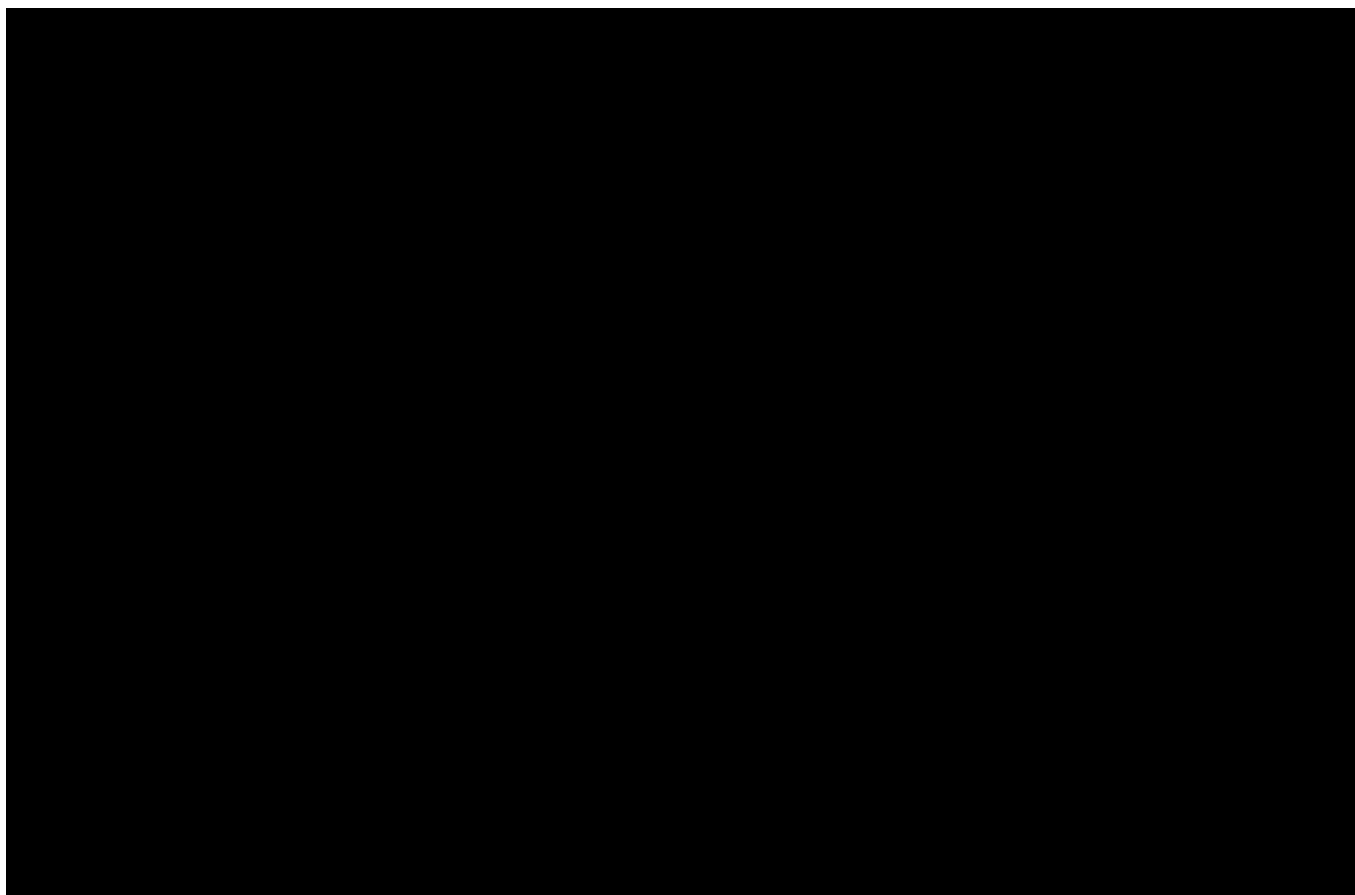












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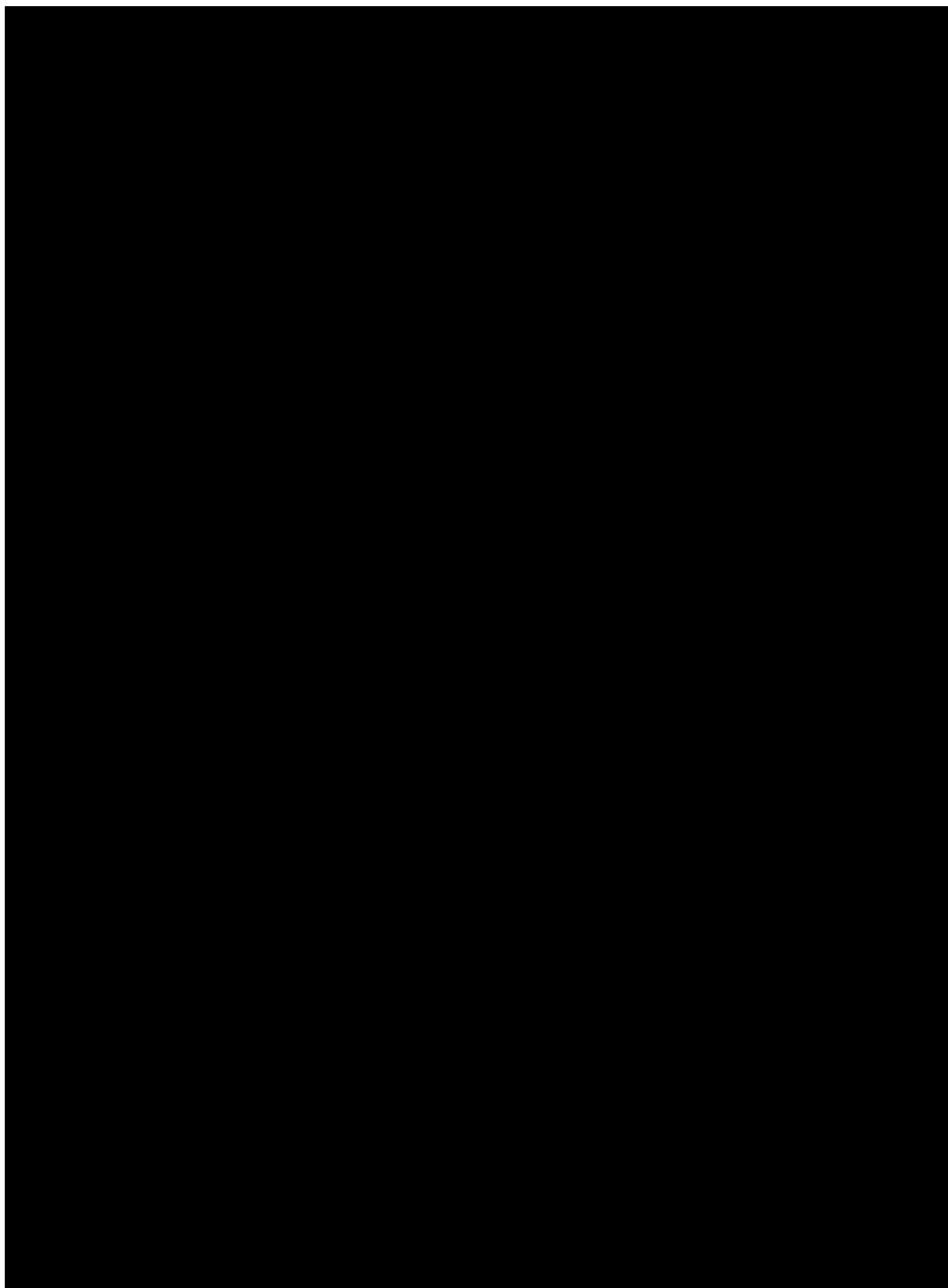
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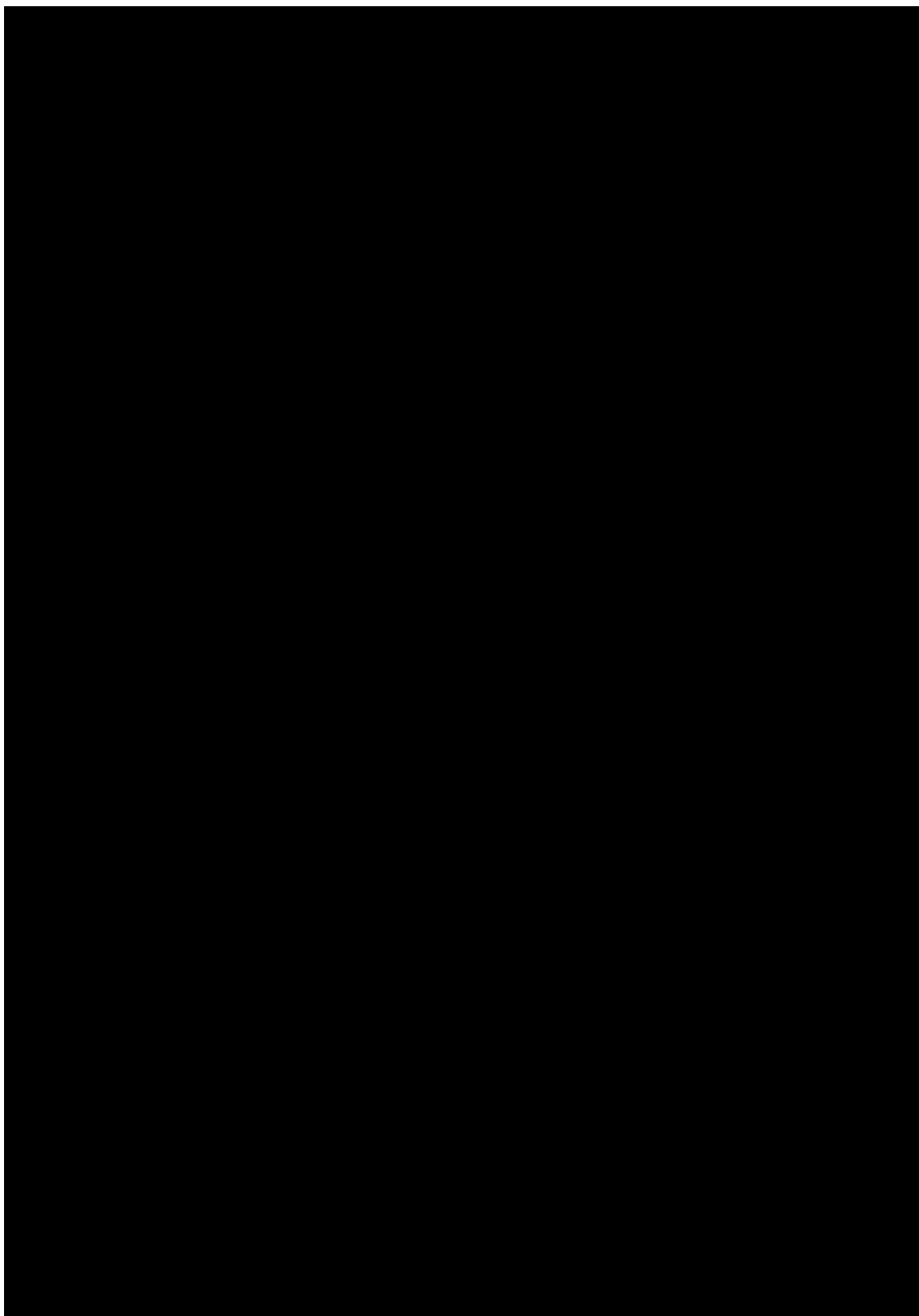
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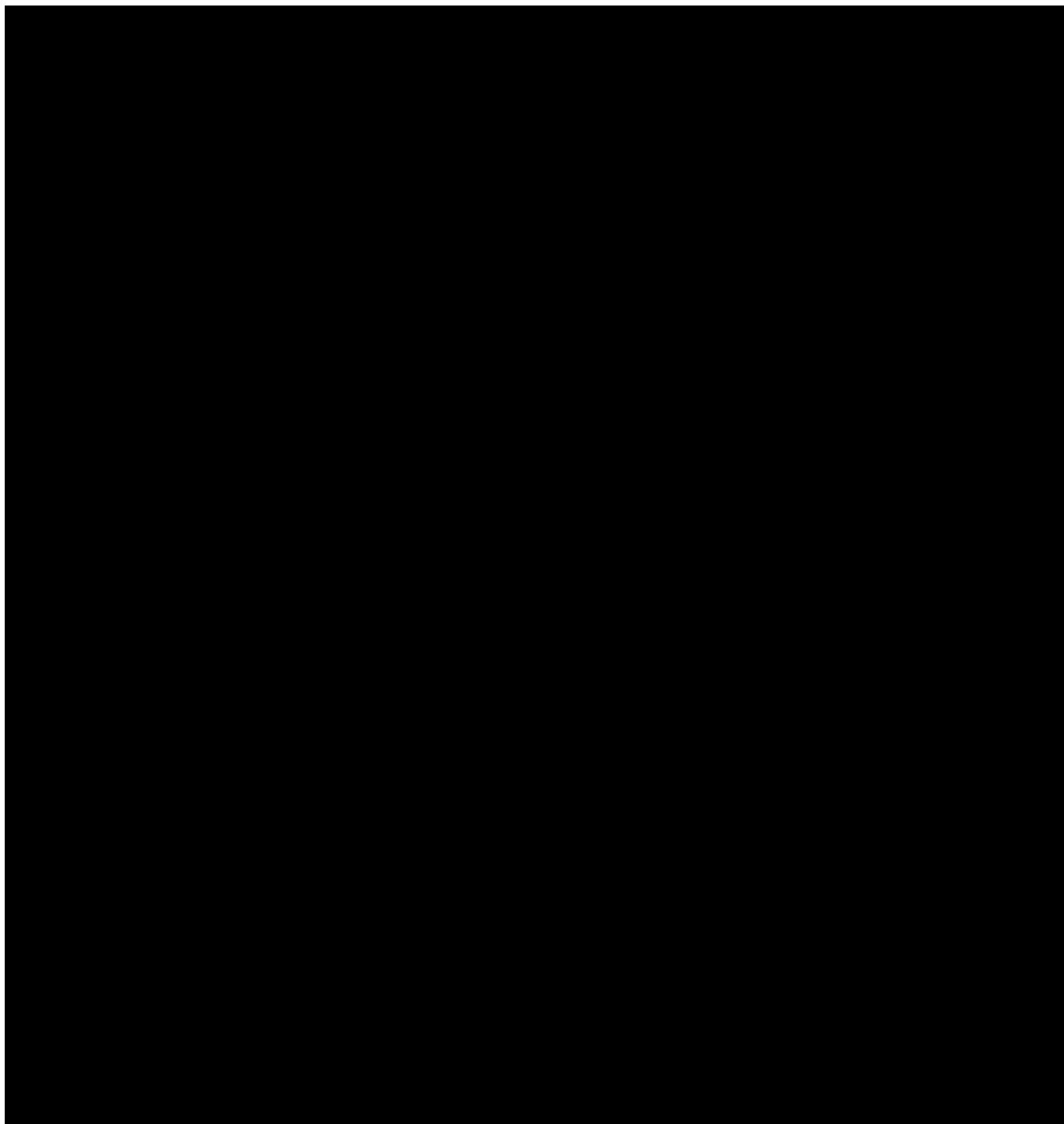
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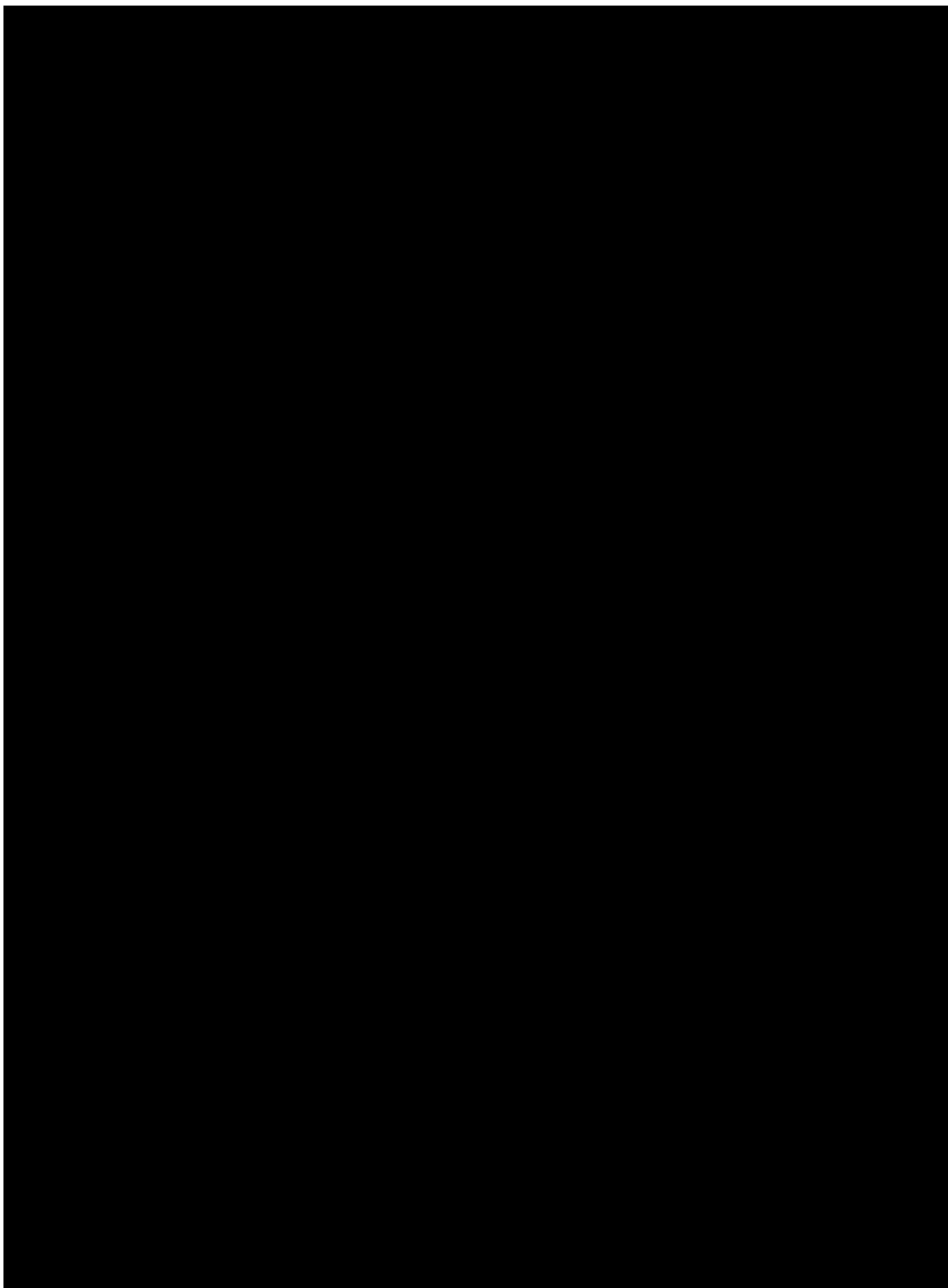
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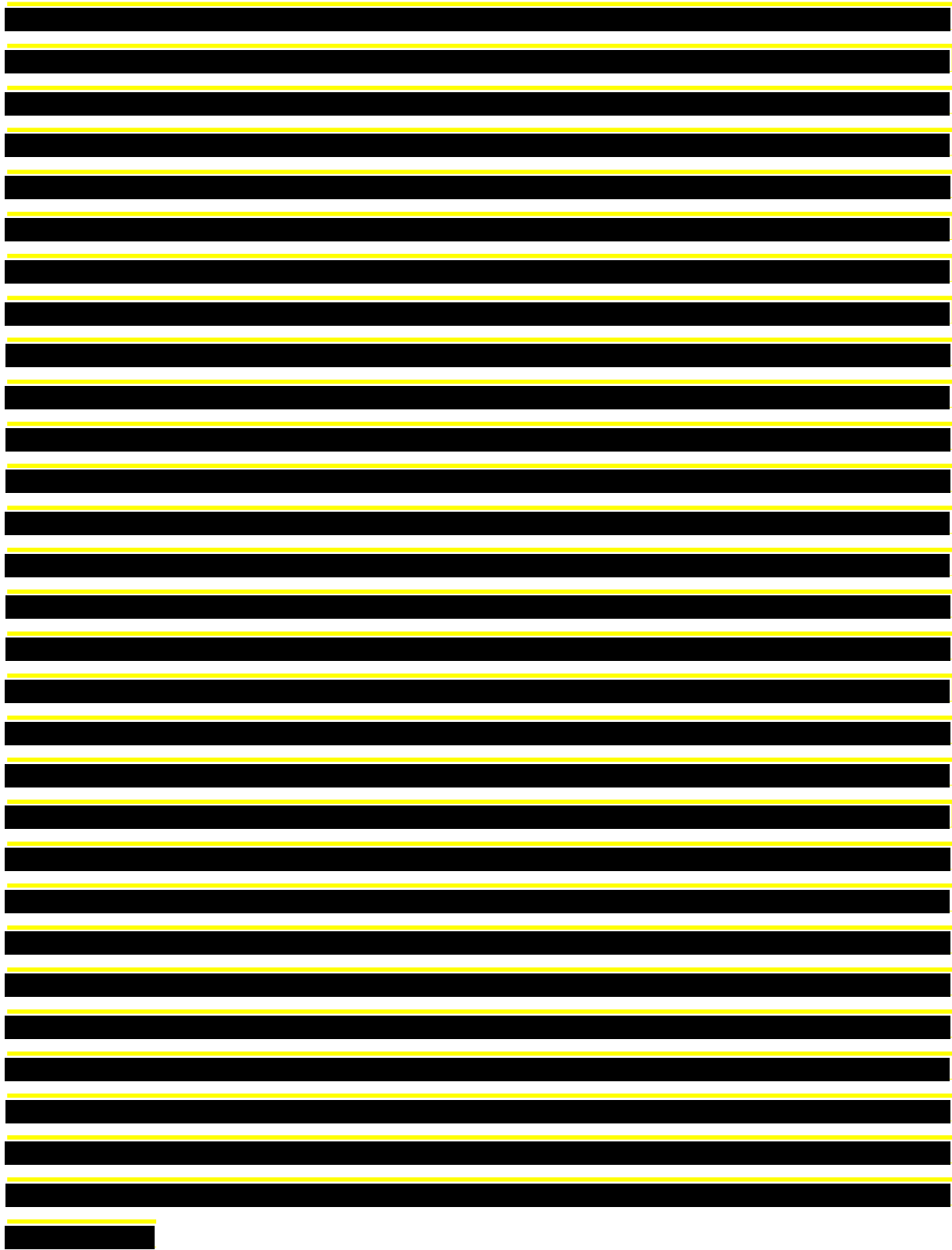
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MZ 22/02/2013

Obwieszczenie Ministra Zdrowia z dnia 22 lutego 2013 r. w sprawie wykazu refundowanych leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych na dzień 1 marca 2013 r.

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№	Nazwa leku	Składnik czynny	Forma dawkowania	Opis	Podmiot odpowiedzialny	Właściciel
1	Levemir 100 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
2	Levemir 300 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
3	Levemir 100 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
4	Levemir 300 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
5	Levemir 100 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
6	Levemir 300 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
7	Levemir 100 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
8	Levemir 300 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
9	Levemir 100 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
10	Levemir 300 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
11	Levemir 100 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
12	Levemir 300 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
13	Levemir 100 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
14	Levemir 300 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
15	Levemir 100 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
16	Levemir 300 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
17	Levemir 100 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
18	Levemir 300 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
19	Levemir 100 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk
20	Levemir 300 mg/ml	insulina detemir	infiltracyjna	szkło szkiełko	Novo Nordisk	Novo Nordisk

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№	Nazwa	Składnik	Forma dawkowania	Wzrost	Ciężar ciała	Wiek
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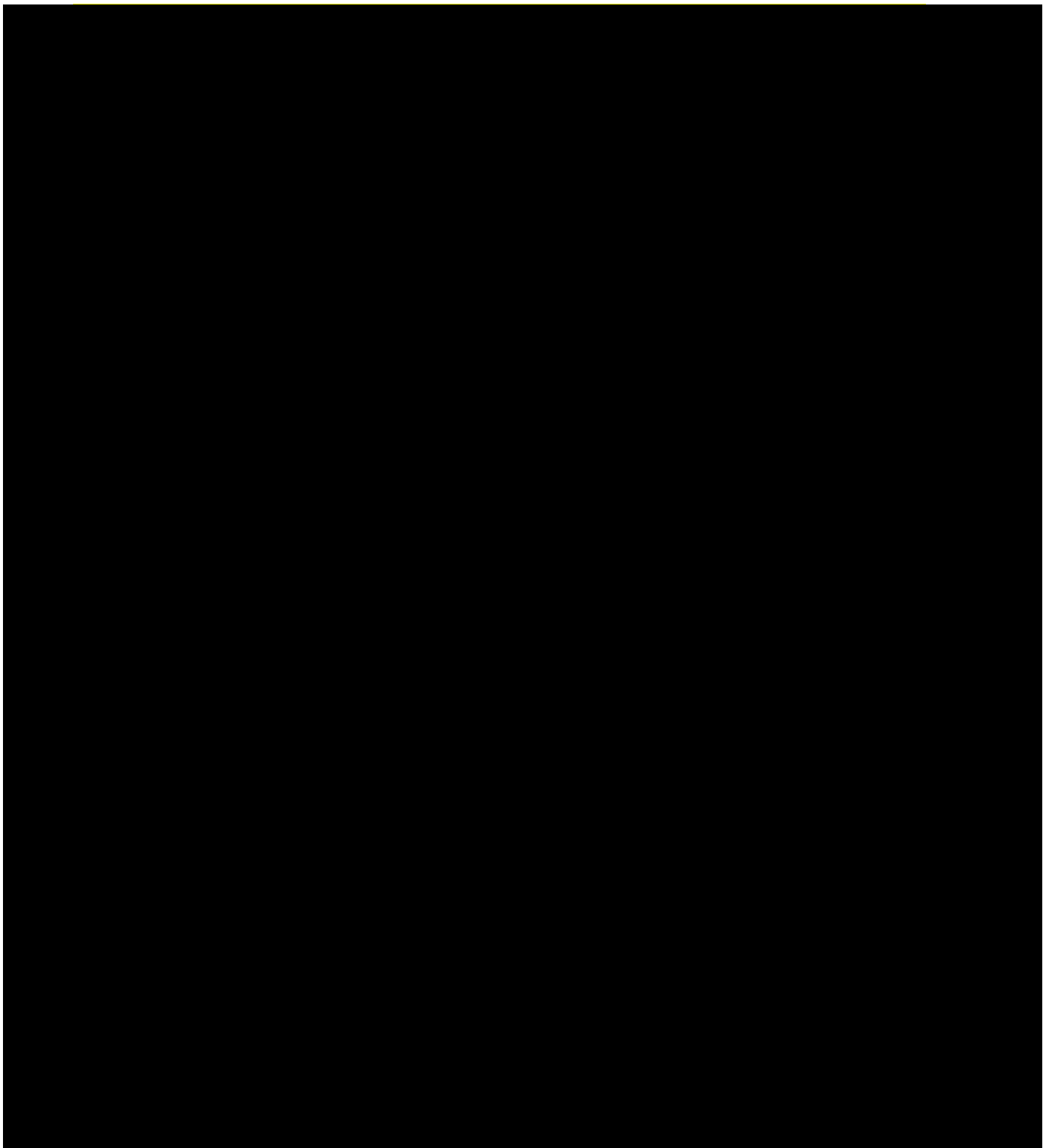
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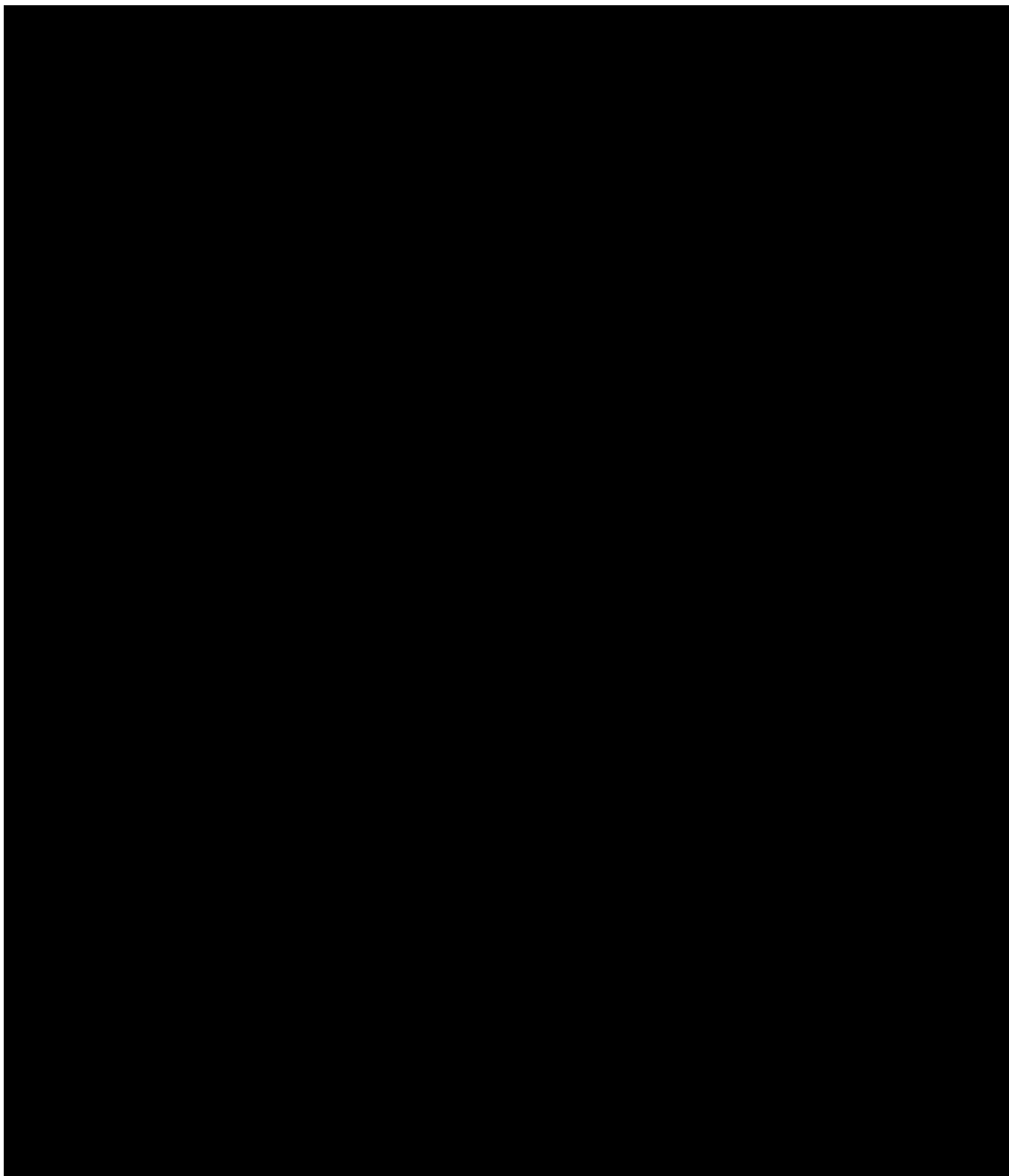
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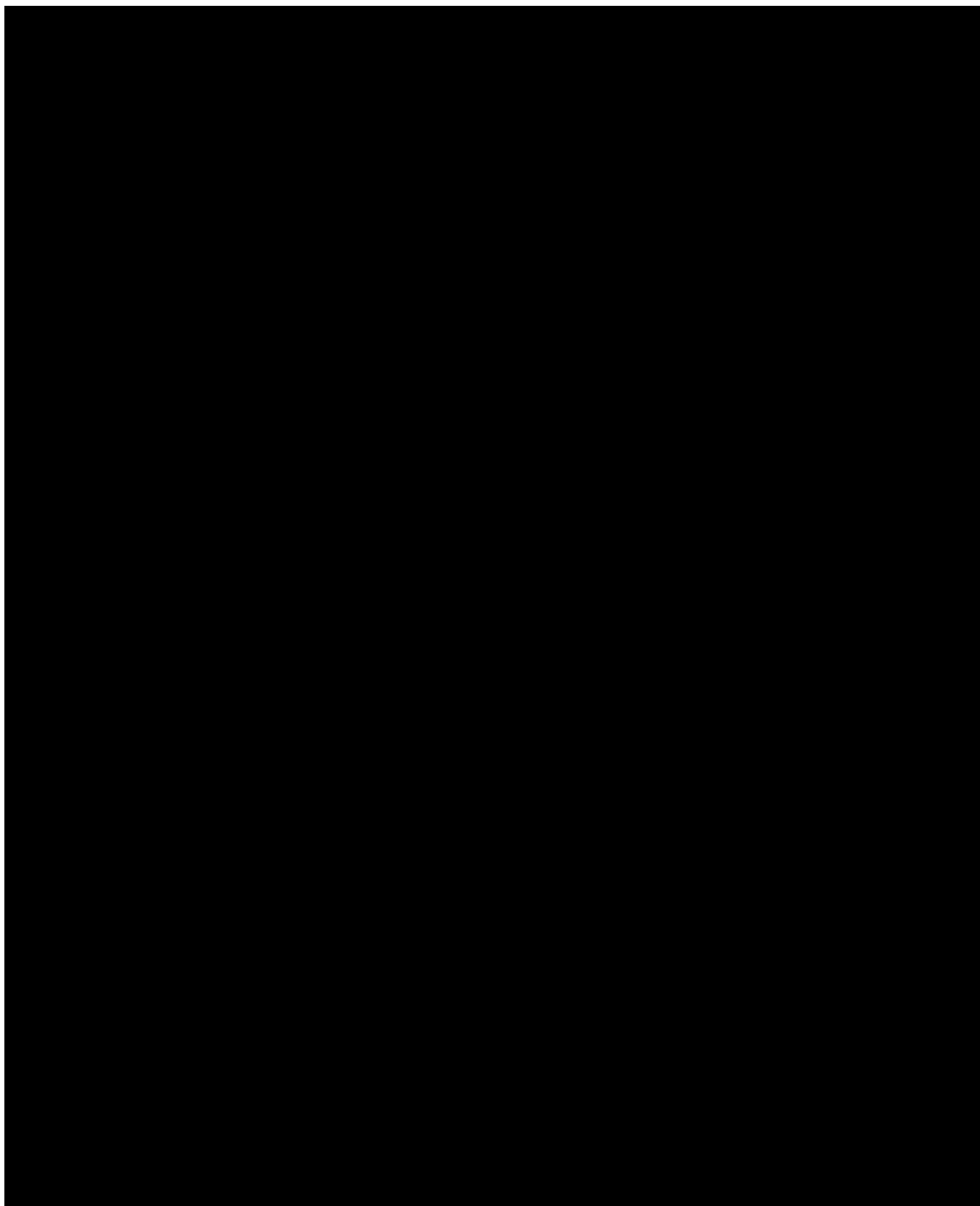
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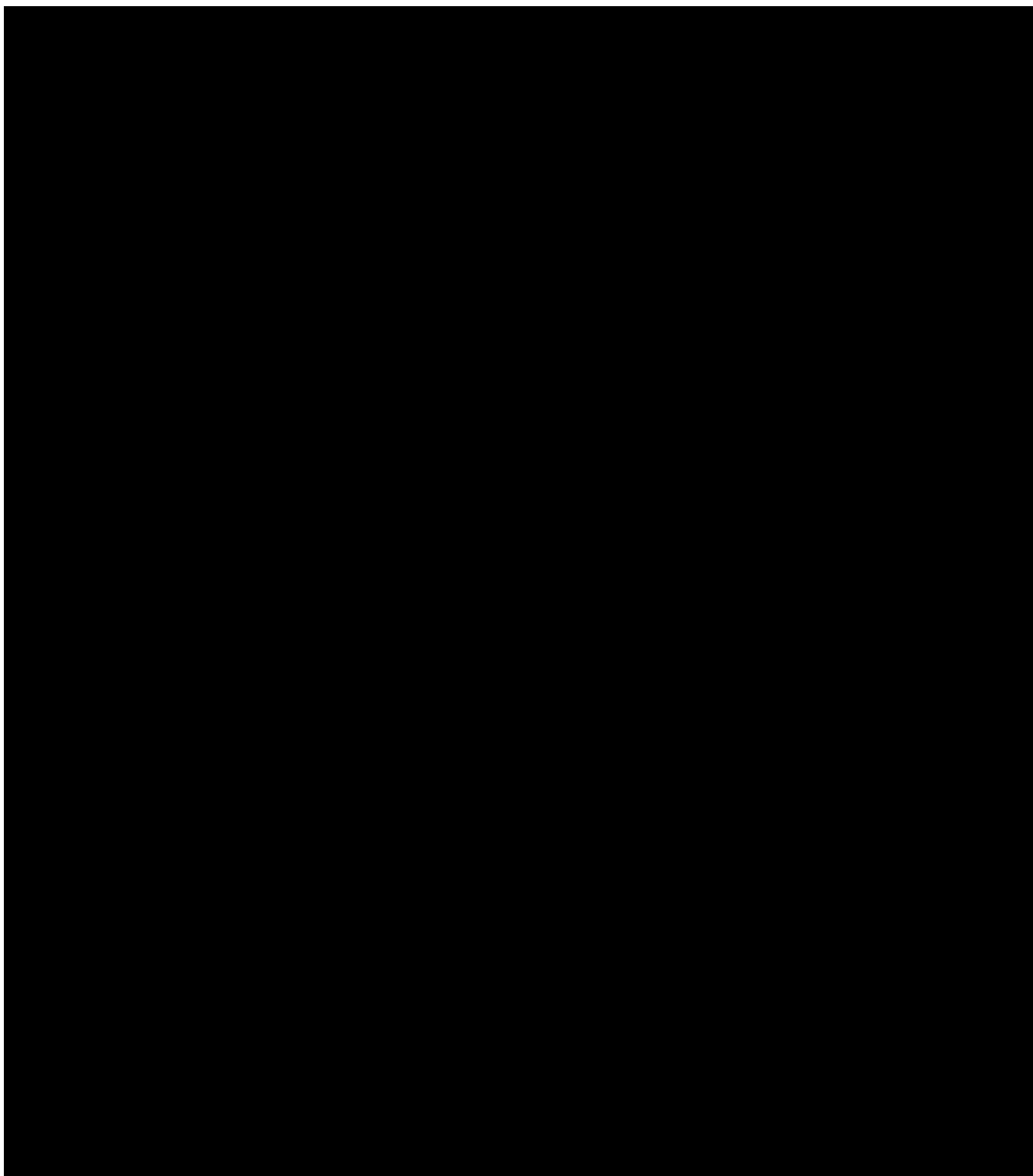
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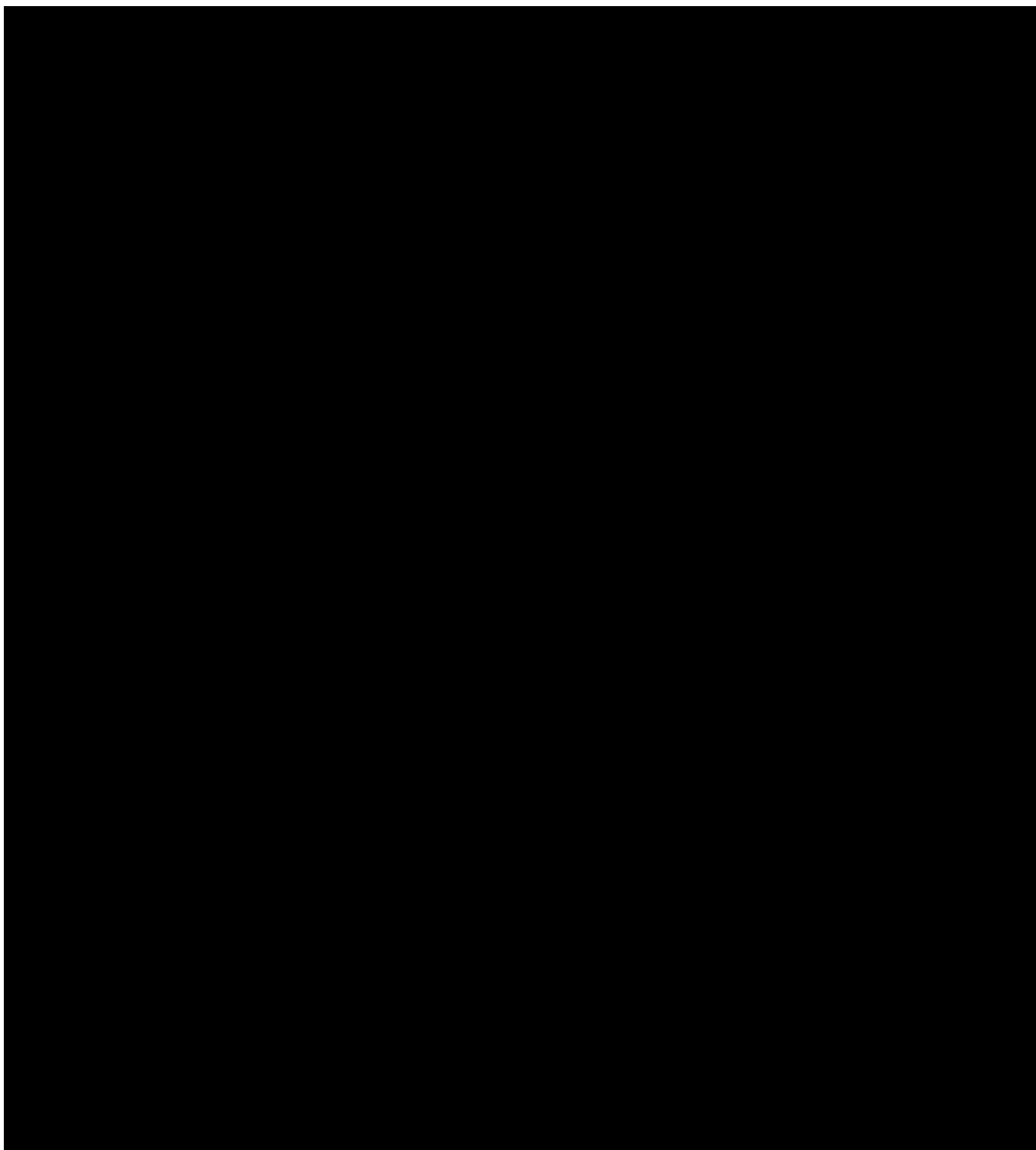
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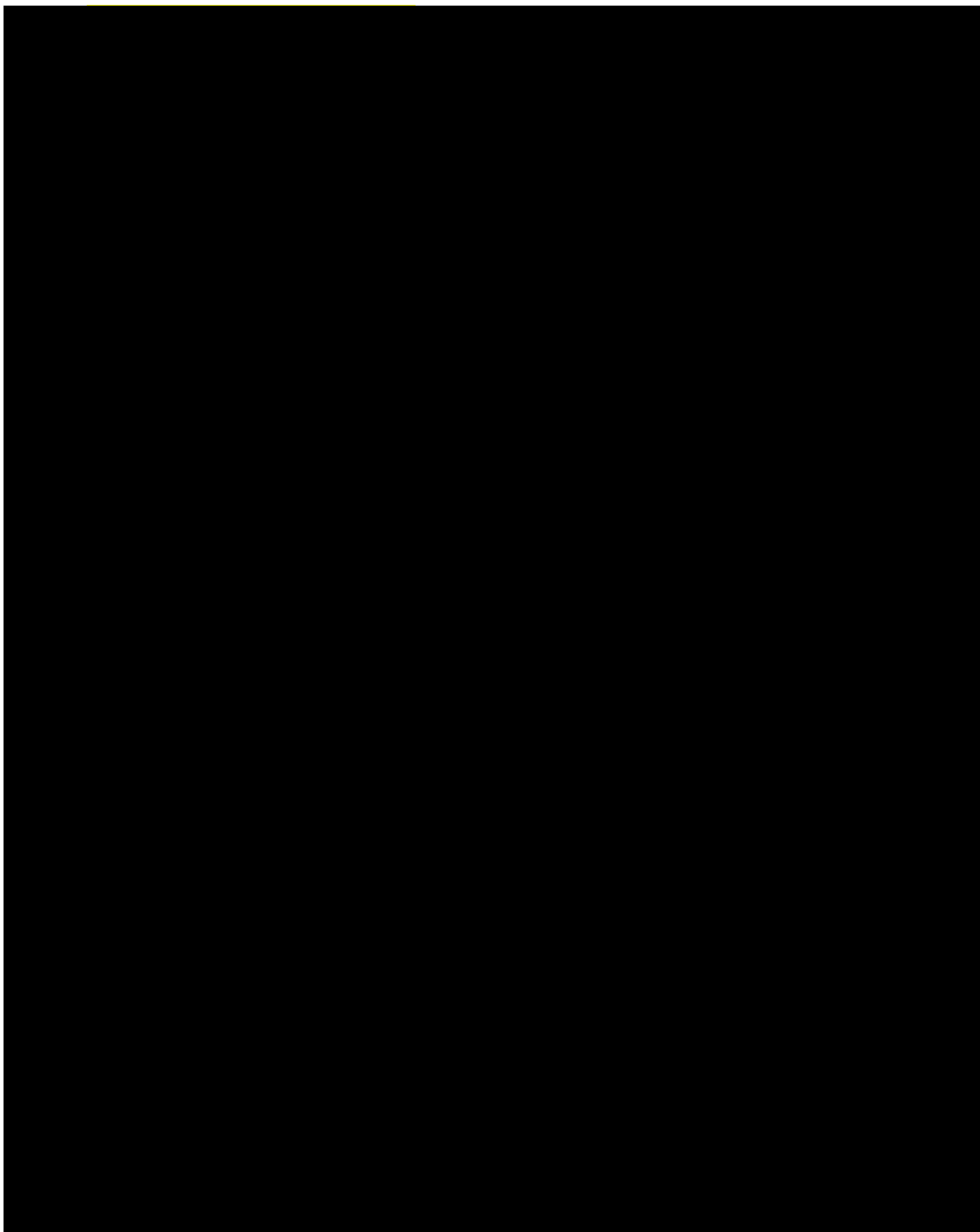


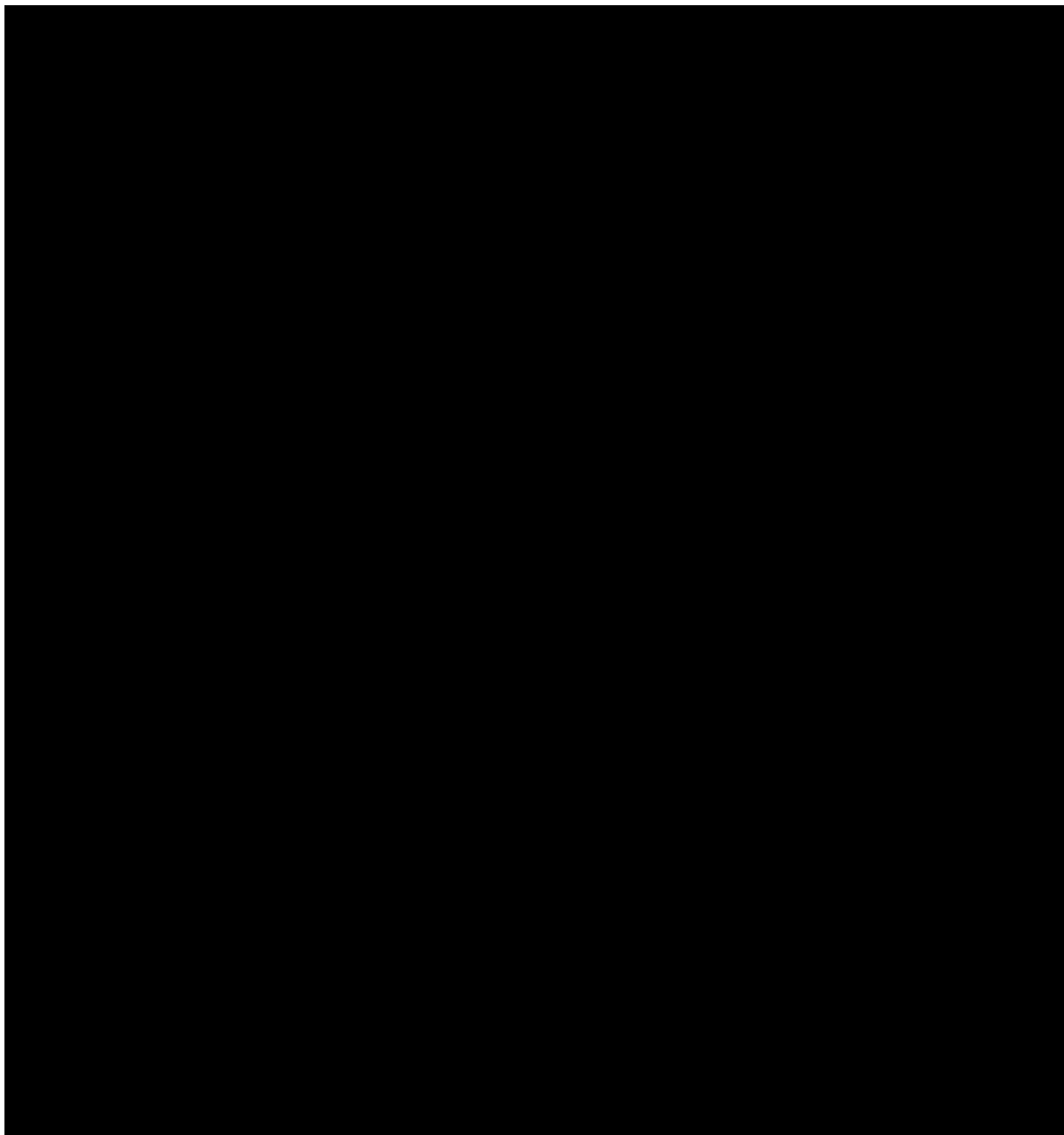


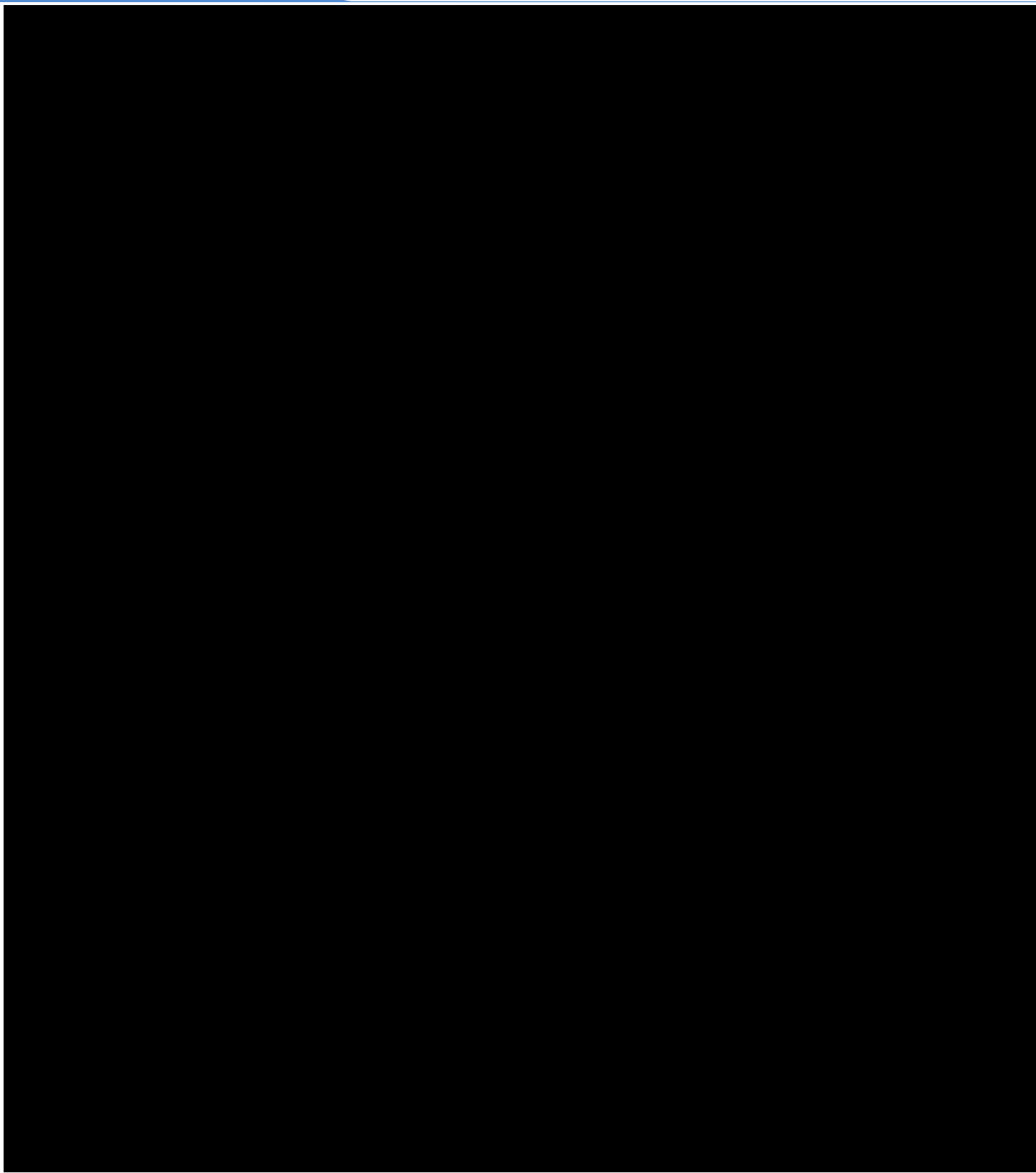


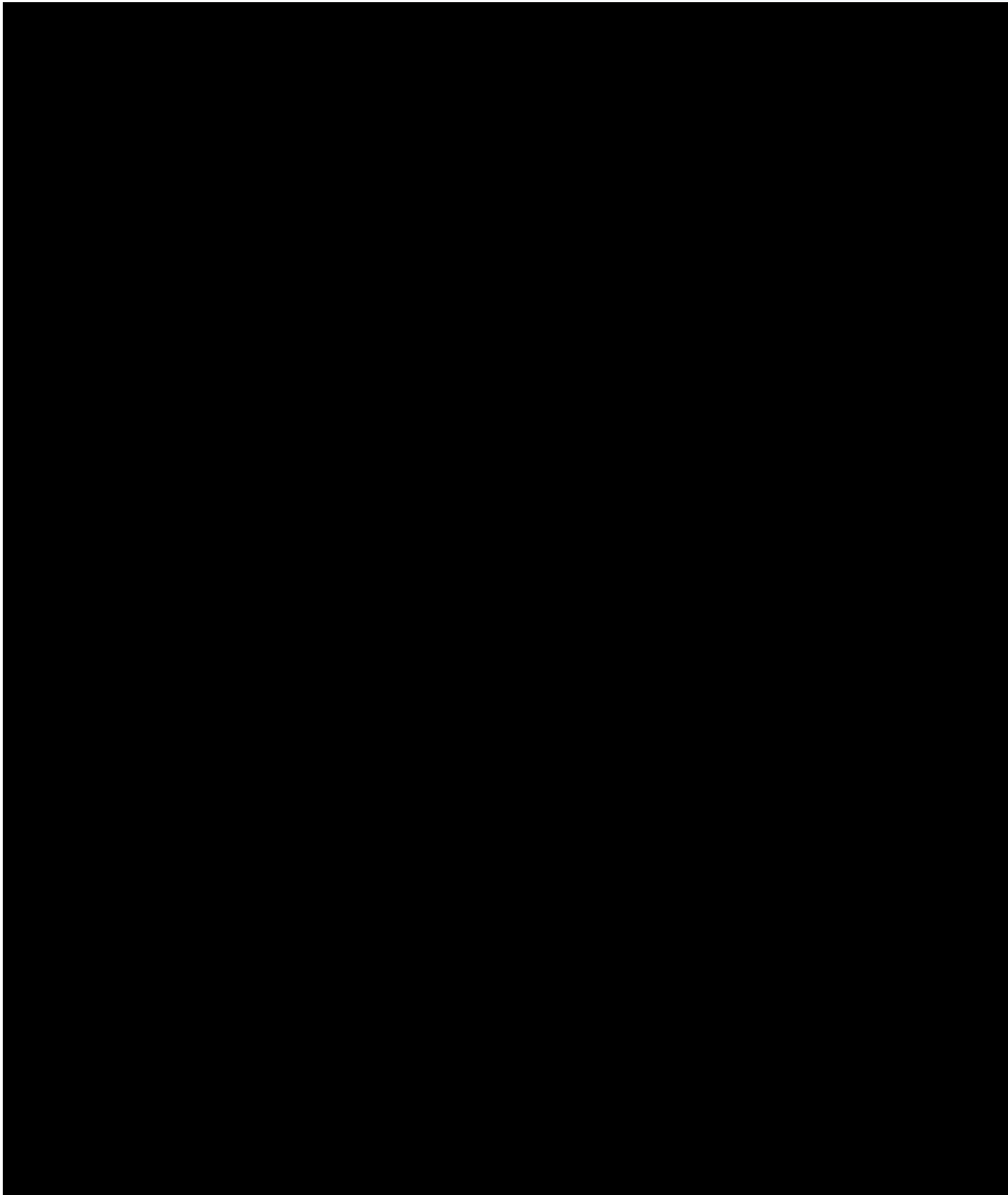


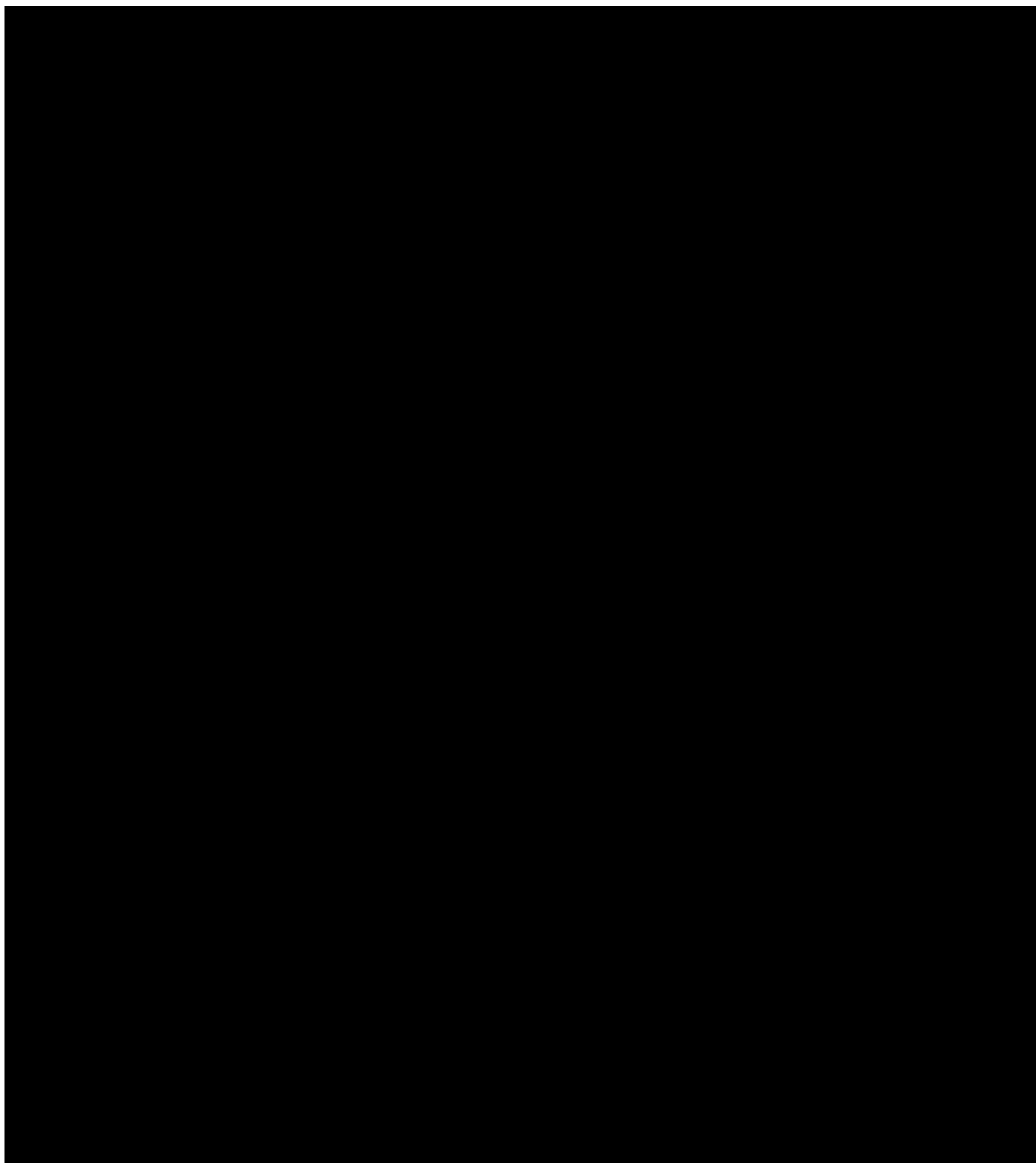


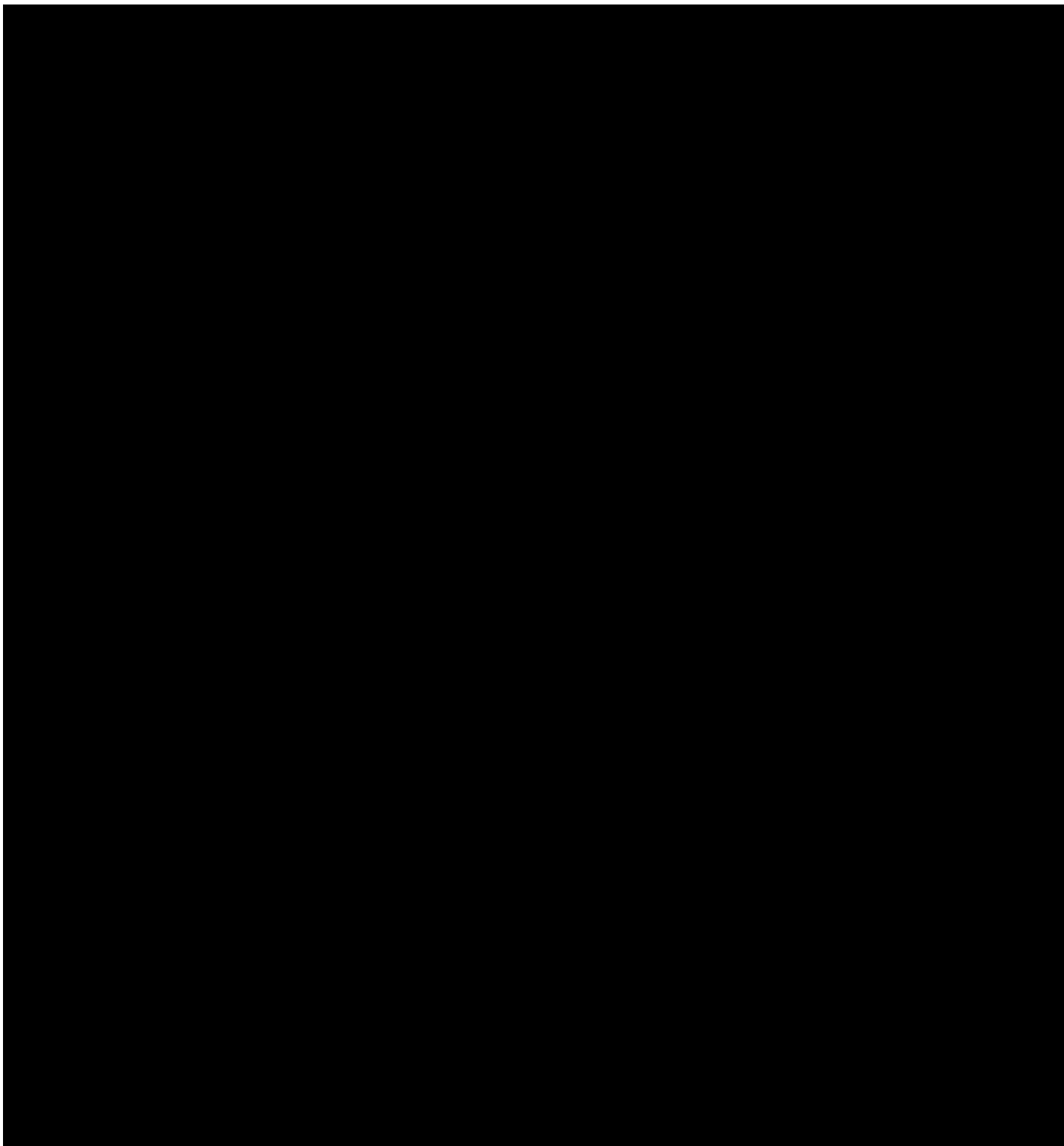


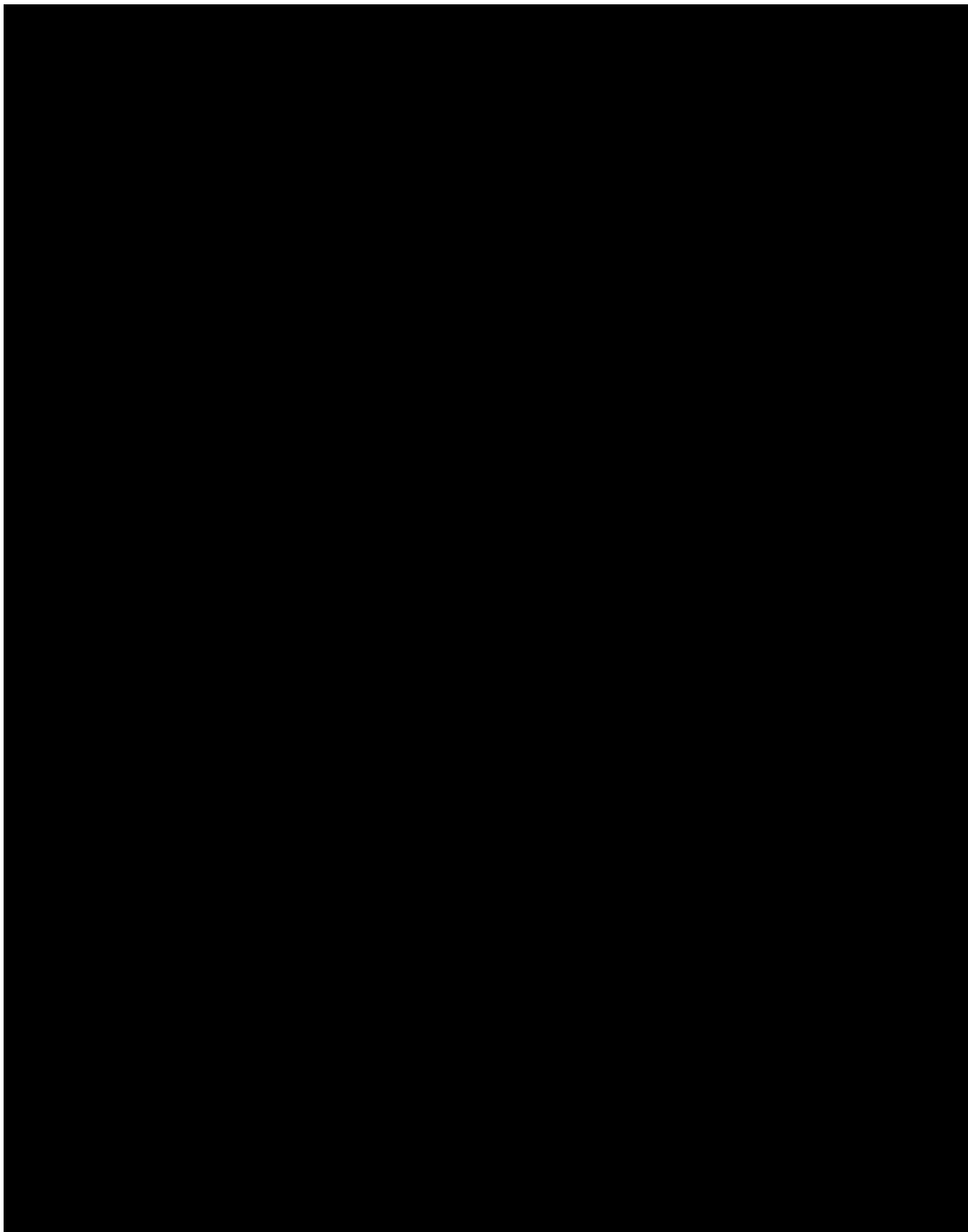


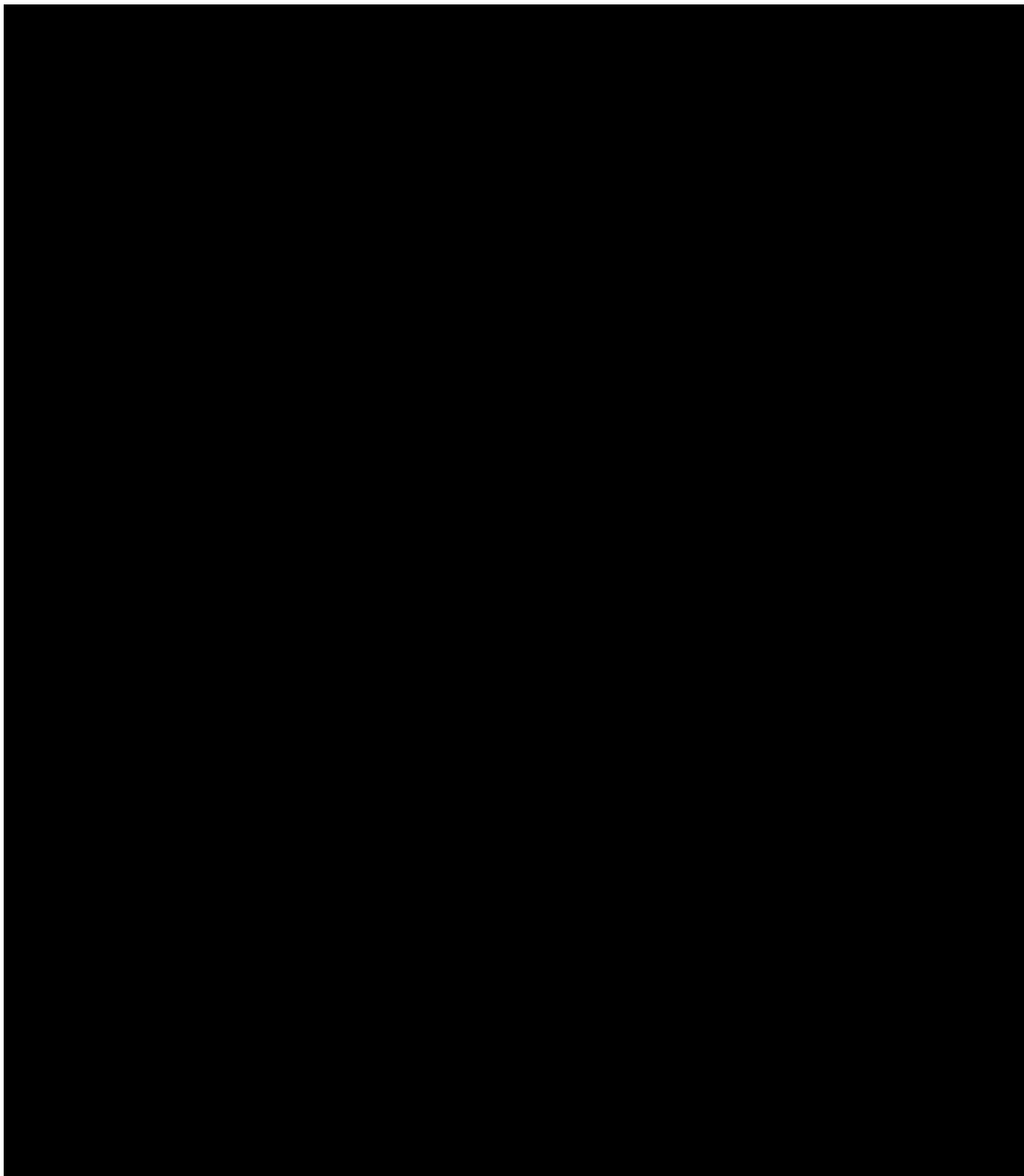


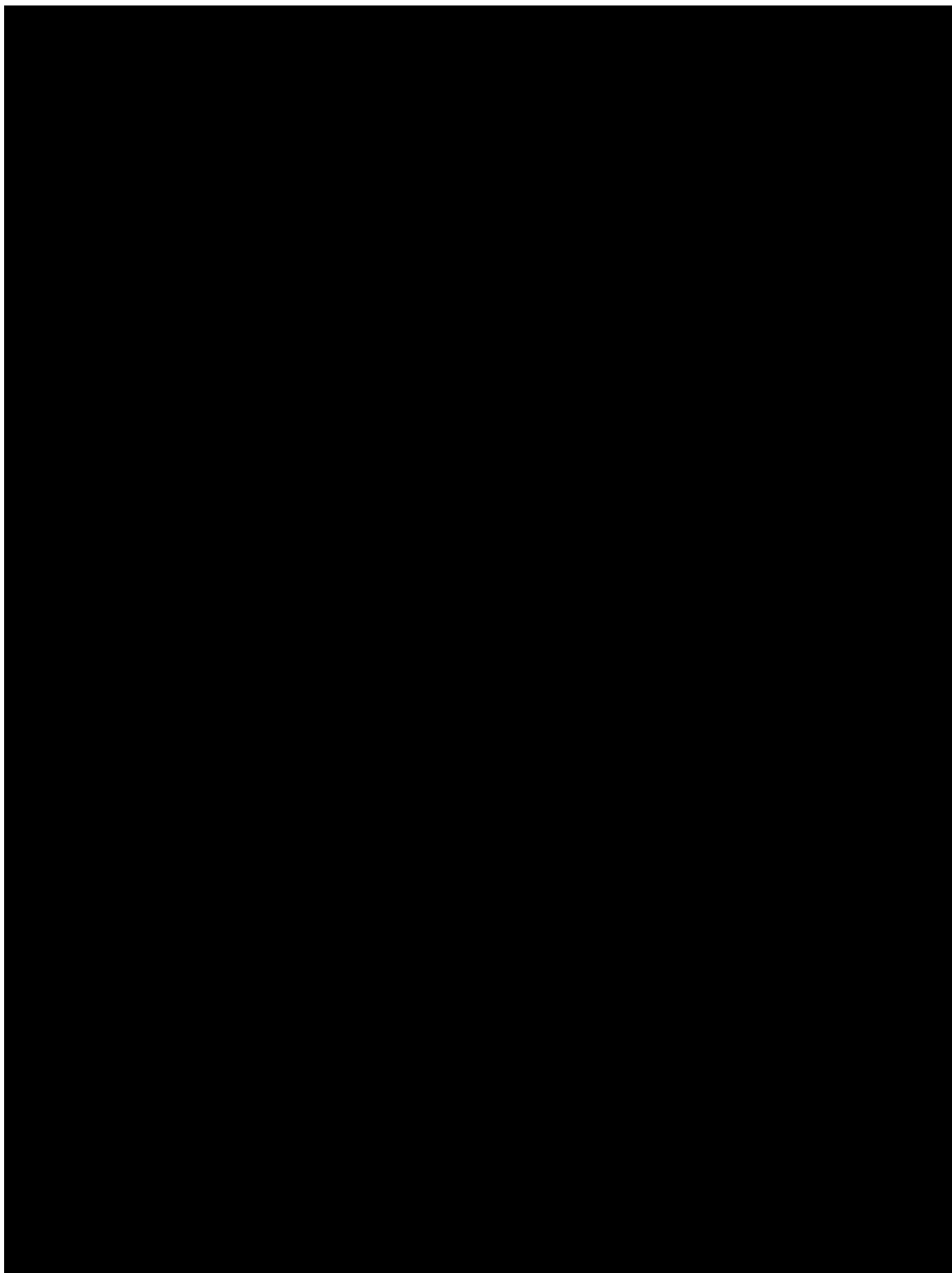












The table consists of approximately 15 rows and 4 columns. The content is almost entirely obscured by black redaction bars. The table structure is visible through the grid lines and the placement of the redactions. The redactions are placed in a way that suggests a structured data table, possibly containing patient information, treatment details, or clinical trial data. The redactions are placed in a way that suggests a structured data table, possibly containing patient information, treatment details, or clinical trial data.

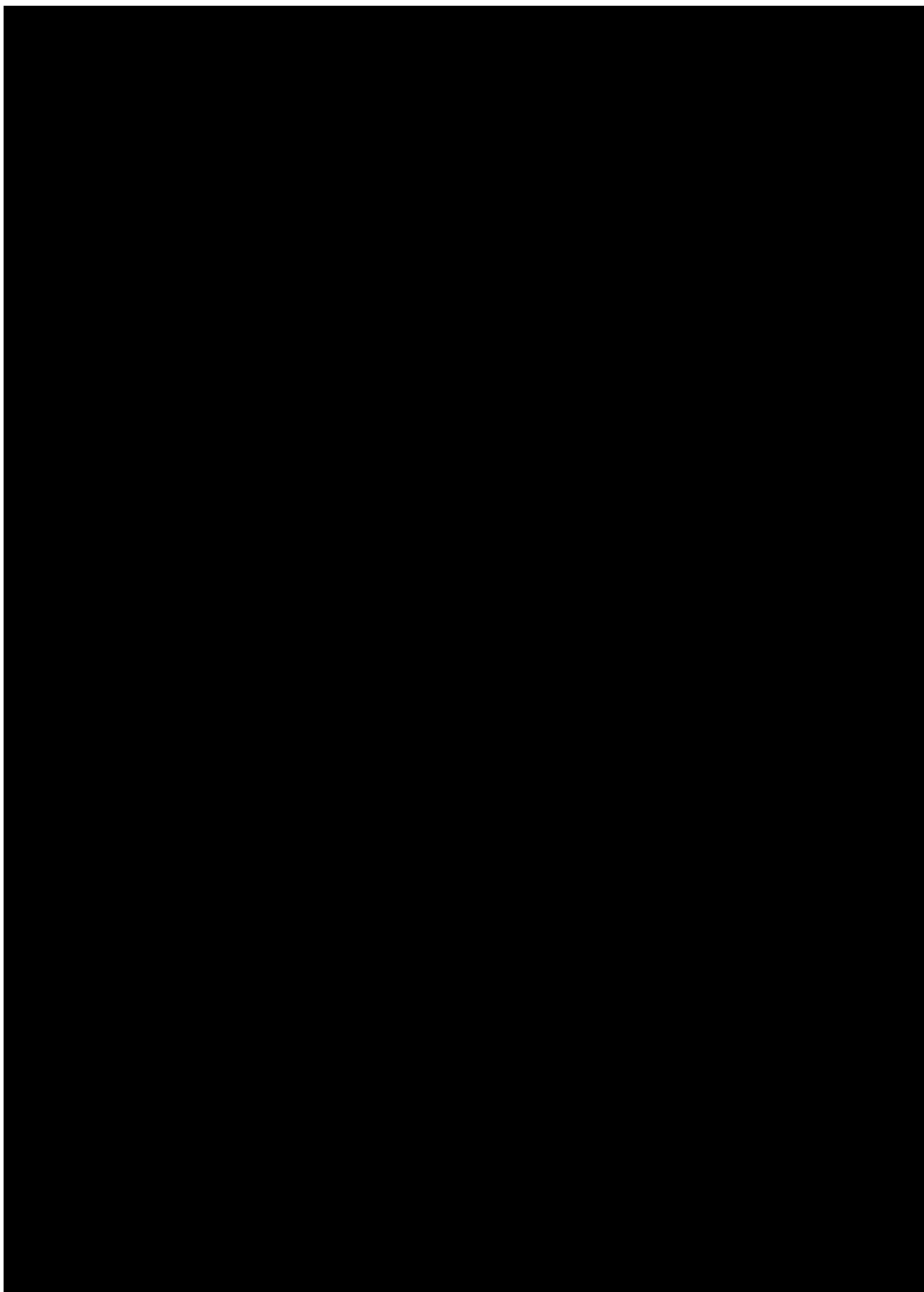
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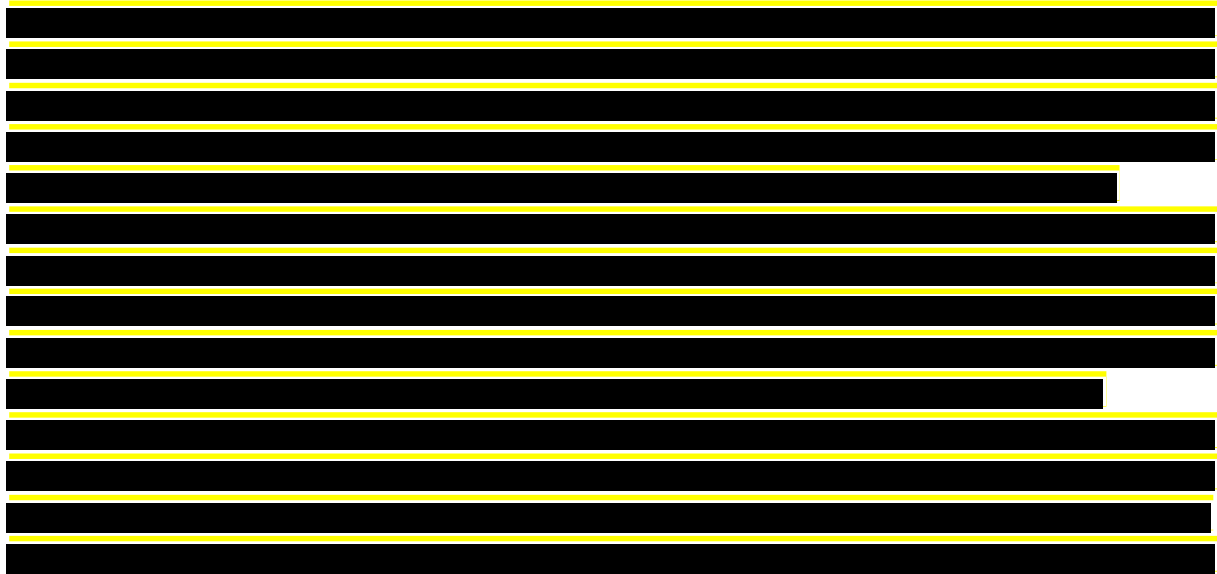
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