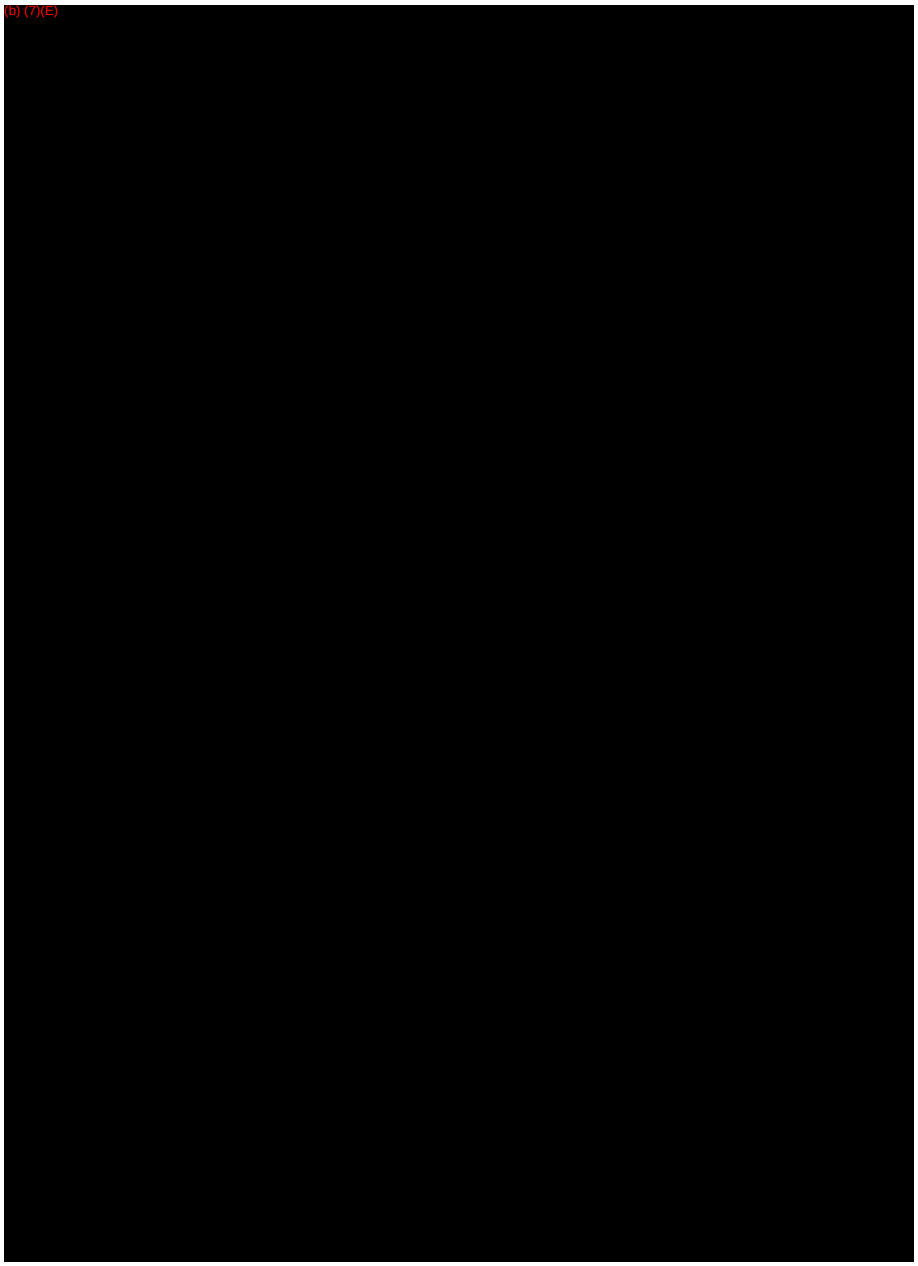
OFFICE OF FORENSIC TOXICOLOGICAL SERVICES

Standard Operating Procedures

2020

IMMUNOASSAY/SCREENING SECTION
90K STREET N.E., SUITE 102
WASHINGTON DC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OFFICE OF FORENSIC TOXICOLOGICAL SERVICES

CHAPTER ONE

INTRODUCTION

The District of Columbia Pretrial Services Agency was the first to introduce onsite drug testing of defendants to supplement interview information with an accurate and objective measure of recent drug use. PSA took advantage of an opportunity to implement an onsite pretrial testing program in 1984 with initial funding from the National Institute of Justice (NIJ). Based on the success of PSA's pilot project, the Bureau of Justice Assistance (BJA) provided funding to five jurisdictions to establish pretrial drug testing demonstration projects. These projects were designed to replicate the District's testing model, incorporating both pre-initial appearance testing and pretrial drug monitoring.

Under the Anti-Drug Abuse Act of 1988, Congress also mandated pretrial drug testing in eight selected federal court districts as a two-year demonstration project. In a subsequent report, the Administrative Office of the United States Courts advocated expanding pretrial drug testing to all federal court districts. On December 18, 1995, President Bill Clinton directed Attorney General Janet Reno to develop and implement a universal policy providing for the drug testing of all federal arrestees before the decision is made to release them into the community pending trial. He also directed the Attorney General to take steps to encourage states to adopt and implement the policy.

To activate the directive at the federal level, in 1996 the Attorney General reached agreement with the federal courts to implement pretrial drug testing in 24 of the 94 federal districts – An initiative called Operation Drug Test. To begin implementing the policy at the state level, Congress increased funding for the Byrne Formula Grant program in FY 1997 by $25 million specifically to encourage state and local jurisdictions to support effective drug testing initiatives at all stages of the criminal justice process, beginning with the pretrial stage.

While 68 percent of pretrial programs now use drug testing, PSA is among only a handful with in-house full-service laboratories. The Forensic Toxicology Drug Testing Laboratory (OFTS) uses Immunoassay and Gas Chromatography Mass Spectrometry (GCMS) methodologies. GCMS is widely recognized in the scientific community as the most specific, sensitive technique that exists for determining the chemical structure of a compound. Whereas many programs only rely on test results that report positive or negative for drug use, OFTS also performs pharmacokinetic interpretations, determining if drug use is new or residual.

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all labs testing human specimens for diagnosis, prevention or treatment of illnesses. The policy of the US Department of Health and Human Services (DHHS), Centers for Medicare and Medicaid Services, which regulates all non-research laboratory testing through CLIA, is that labs performing drug and alcohol screening and/or testing followed by individual treatment must be CLIA-certified. A 2008 survey of agencies testing probation and parole populations conducted by the American Probation and Parole Association found that the vast majority of respondents did not use CLIA-certified laboratories. OFTS is certified by

The mission of OFTS is to serve and support the mission of the D.C. Pretrial Services Agency and the Court Services and Offender Supervision Agency by:

- Providing laboratory data that is timely, scientifically correct, and forensically sound.
- Providing scientific and forensic information thorough scientific presentations and discussions to D.C. Pretrial Services Agency and Court Services and Offender Supervision Agency

- Providing expert testimony in forensic toxicology at judicial proceedings
- Maintaining a professional ethical practice in forensic toxicology.

To accomplish this OFTS has established a quality system with the continuing confidence that laboratory data is accurate, impartial, and relevant.

It is imperative that all work conducted by OFTS be of the highest quality possible while congruent with the needs of the D.C. Pretrial Services Agency and court communities that it serves. This applies to the actual technical laboratory work performed, written reports, and courtroom testimony provided by the toxicologists and chemists.

Technical competency can be achieved only by the combination of a number of components such as initial training, experience, continuing education through professional development, proficiency testing, and an appreciation of the scientific protocols and methodology, all of which must be projected against a background of proper professional ethic.

Forensic work does not permit the rationalization of substandard work. It is widely expected that all work be exemplary; a nything less than exemplary may be subjected to criticism. Whether that criticism is fair or unfair is not an issue; the adversary nature of our system is such that criticism will in fact ensue.

OFTS INFORMATION

SERVICES:

LAB HELP DESK

LAB HELP DESK LEVEL
This mailbox is used to request pharmacokinetic interpretations of laboratory results. The P.O.C. is the Laboratory Operations Director and Supervisor, Immunoassay Unit. The system is designed to interpret a maximum of four specimens per PDID per request.

LAB HELP DESK PRESCRIPTION (Prescr)
This mailbox is used to request information about prescriptions presented by clients to CSO/ PSO.

OFTS CONTACT INFORMATION

ADDRESS:
90 K Street N.E., Suite 102
Washington, DC 20002
Phone: (202) 585-7266

DEFINITIONS

Distribution – The process of circulation throughout the body. Blood (a fluid tissue) is the primary mediator (substance which transmits another substance) of materials throughout the body. Through the bloodstream, various substances reach, lodge, and concentrate in various tissues in differing amount, producing different toxicological effect.

V_d -Volume of distribution

Drugs of Abuse – Potentially addictive drugs that are taken to induce pleasure

Elimination – The metabolic and excretory mechanisms that result in the removal of a drug(s) From the body

First Order Elimination – A specific percentage (½) of the drug is eliminated in a specific time and is characterized by elimination half-life ($t_{½}$)

Zero Order Elimination – A specific amount of a drug is eliminated in a specific time.

Immunoassay – Immunoassay systems rely on specific antigen-antibody reactions for detecting analytes of interest in a variety of sample matrices. Examples are Radioimmunoassay (RIA), Enzyme Immunoassay (EMIT, ELISA, CEDIA), and Fluorescence Polarization Immunoassay (FPIA).

PCP – Phencyclidine

THC- Δ9 tetrahydrocannabinol

K2- Synthetic Cannabinoid (SC)

EtG- Ethyl Glucuronide

6-AM- 6- acetyl Morphine

Pharmacology –

Pharmacokinetics – Describes what the body does to a drug, including the processes of absorption, distribution, metabolism, and excretion.

Pharmacodynamics – Describes what a drug does to the body.

LAB REFERENCES

Goodman & Gilmans, The Pharmacological Basis of Therapeutics 10th Edition

AAFS, Marijuana Symposium, 1999

SOFT, Marijuana Symposium, 2000

Steven Karch, Drug Abuse Handbook, 1998

Steven Karch, Karch's Pathology of Drug Abuse, 2002

Baselt, R. & Cravey, R., Disposition of Toxic Drug and Chemicals in Man, 6th Edition

Goldberger, BA, et. al., Intrasubject Variation of Creatinine and Specific Gravity Measurements in Consecution Urine Specimens of Heron Users-Clinical Chemistry

Notice to HHS Certified Laboratories and Inspectors. Specimen Validity Testing, SAMHSA, July 29, 1999

Van Dyke, C, et. al., Urinary Excretion of Immunologically Reactive Metabolite(s) After Intranasal Administration of Cocaine As Followed By Enzyme Immunoassay-Clinical Chemistry 1977; 23: 241

Drug Testing Procedures Handbook, US Department of Transportation, 9352:22

History of Cocaine, Steven Karch

LABORATORY and SCIENCE

A laboratory's product is primarily the service it provides in test result information and consultation, but it involves more than just turning out a test result. The most important attributes of that product are:

Technical quality
Informative results
Available test menu
Turnaround time of results
Superior service (e.g. easy access, responsiveness, professionalism, and courtesy)

Attention to these attributes is the foundation for success in the laboratory. It is how a laboratory provides value to its users.

Quality Control (QC)

Quality Control applies statistical process to detect changes that may exceed the quality requirements in the analytical procedures. The measurement process includes the equipment, reagents, calibration processes, personnel, and policies used to produce a measurement of an analyte. Note that before a method is put into routine use, method evaluation protocols must ensure that the procedure has the necessary precision, accuracy, sensitivity, specificity, and stability to meet the clinical needs of the patient population served by the institution. Once the method is stable, QC rules are applied to monitor the component material to assess whether any individual run or point is within acceptable limits.

TRAINING PROGRAMS

Each supervisor is responsible for the establishment and maintenance of a training program for his/her area of responsibility.

The training program is developed based on the skills, knowledge and level of competency required for successful job performance.

The scientists must understand the principles, applications and limitations of the methods, procedures and equipment used. No amount of validation or standardization of procedures will eliminate the need for exercising of sound, scientific judgment

All newly assigned personnel will undergo a training program to assure that they are adequately trained. The extent of the initial training period is dependent upon the individual's previous work experience, educational background and level of competence.

PROFICIENCY TESTING

OFTS's proficiency-testing program should monitor both the capability of individual analyst as well as the effectiveness of the laboratory. Proficiency testing is both internal and external. The proficiency test program may include declared or blind specimens or other audit procedures.

Blind testing provides the best means of assessing the laboratory's performance since no special attention is given to these specimens, as may be the case in open proficiency testing. Therefore,

specimens that contain a known amount of analyte (drugs) will be treated by the staff technicians in the same way and under the same conditions as regular specimens.

Blind proficiency testing consists of two types, external and internal. For Screening, OFTS uses external blind proficiency testing submitted by the American Association of Bioanalysts (AAB).

PROCEDURE DEVELOPMENT

Each supervisor develops and documents all the procedures and methodologies used in OFTS and the Director validates the procedures.

Each procedure in use throughout OFTS should include the following information where appropriate:

- Testing procedures to be used.
- Step-by-step instructions of the logical progression of the analysis.
- Calculations as required with the expected accuracy and precision.
- References to the literature.

The capacity of a method to maintain both accuracy and precision is a measure of its reliability. If a procedure has demonstrated consistent accuracy and precision over an extended period of time then the method can be considered reliable. The reliability of a procedure can only be established by checking the method, using appropriate primary standards and controls.

In order to control all the steps of a procedure, it is necessary to use analyzed control material, which is similar in composition to the unknown specimen. The control specimen is then carried through the entire test procedure in parallel with the unknown, affected by any and all variables that affect the unknown. Use of control material is one way to check on the procedure, techniques, reagents, and instrument calibration.

CHAPTER TWO

PERSONNEL, ADMINISTRATIVE, AND GENERAL PROCEDURES

LABORATORY SECURITY

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PERSONNEL DISCLOSURE PROTOCOL

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D.C. Pretrial Services Agency
Laboratory Section
Personnel Disclosure Form

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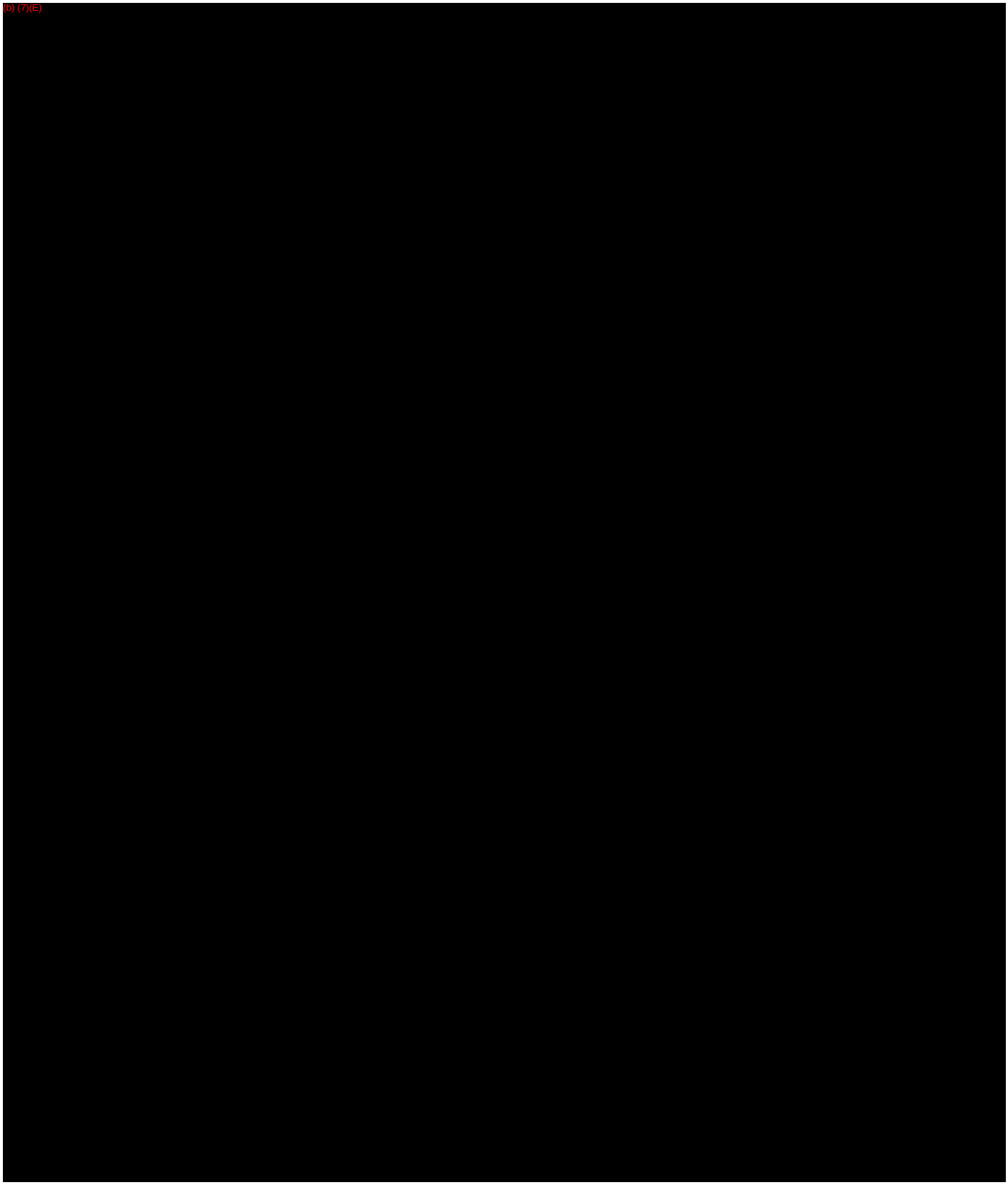

SPECIMENS PROCESSING

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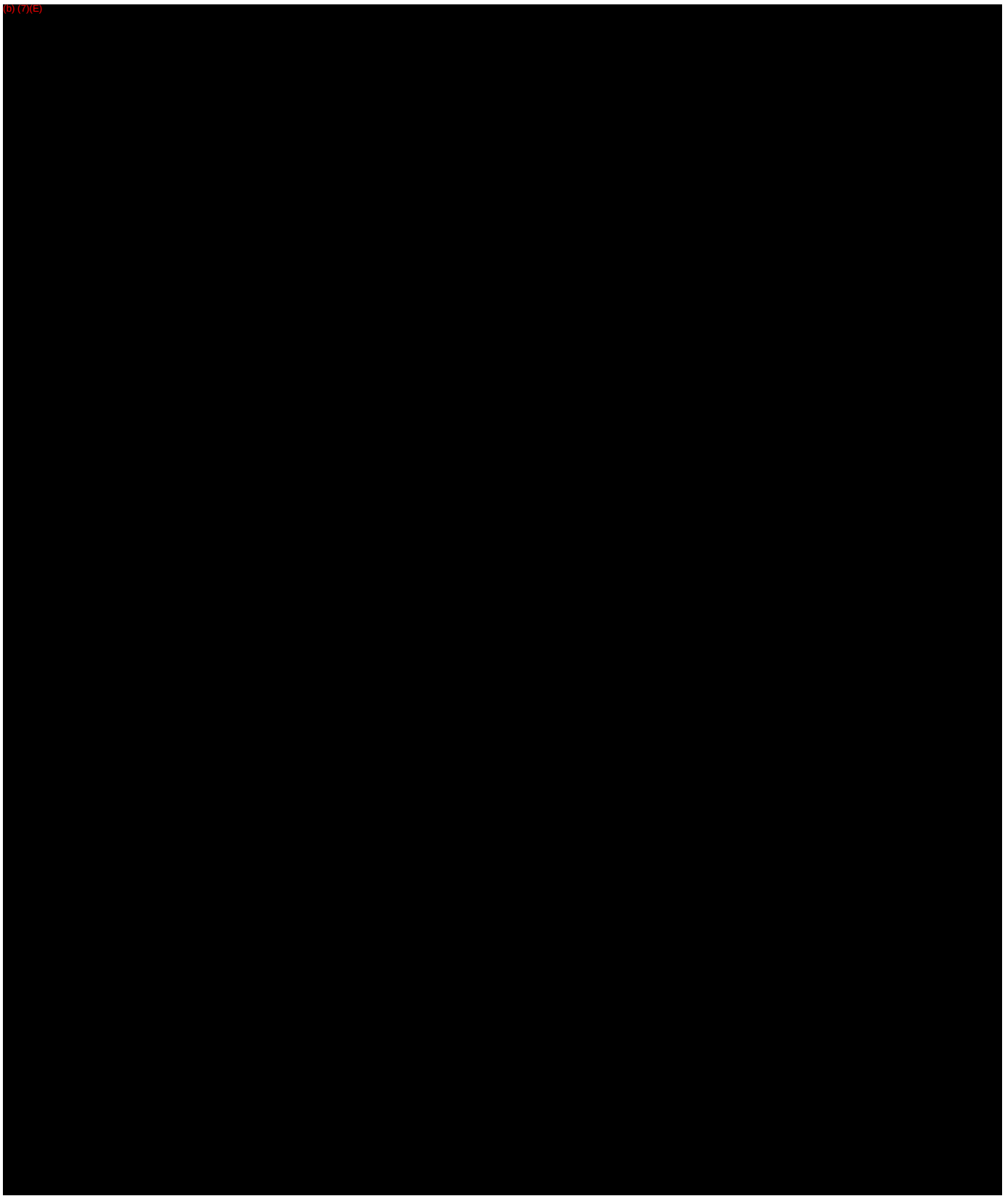

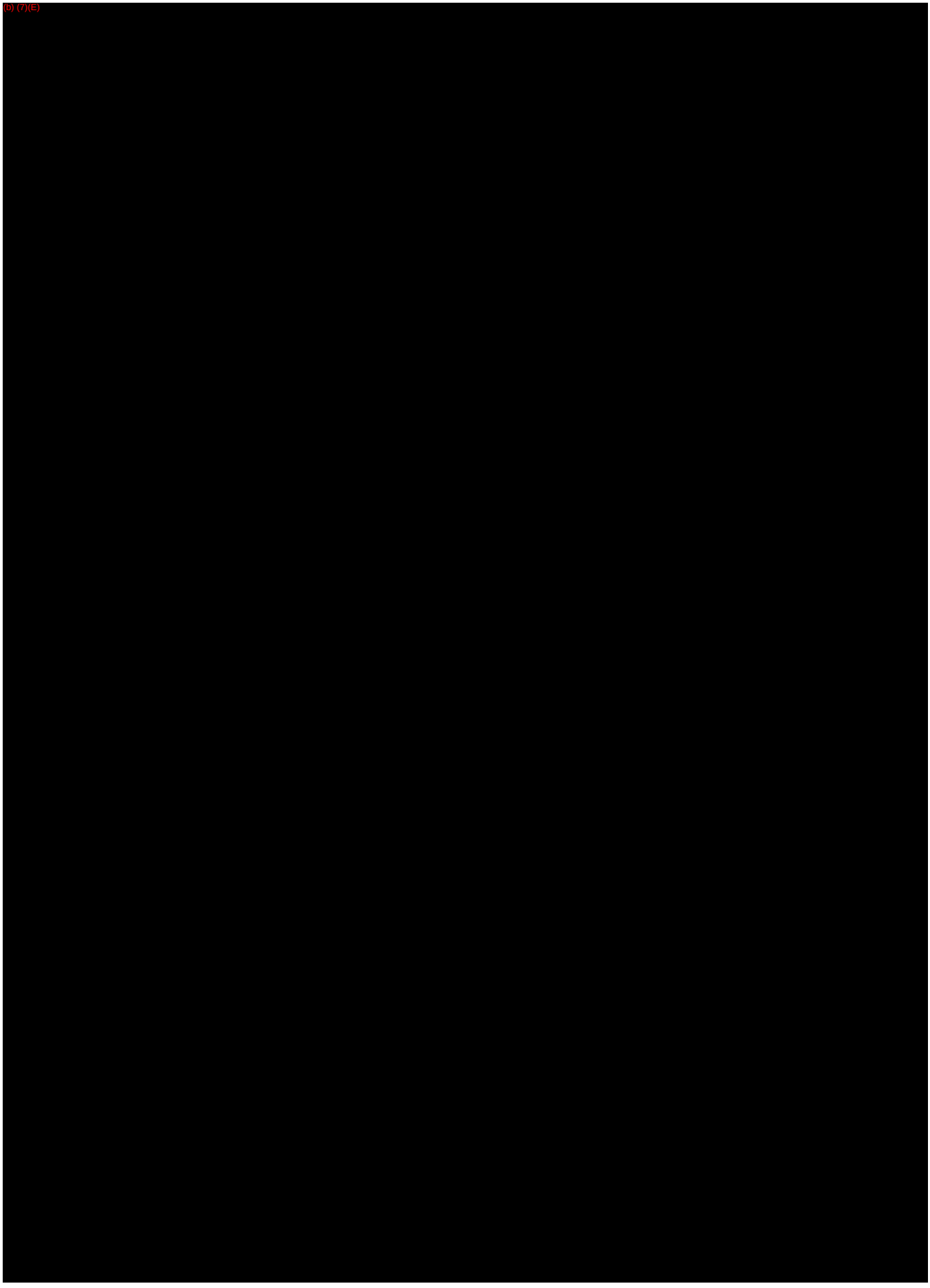
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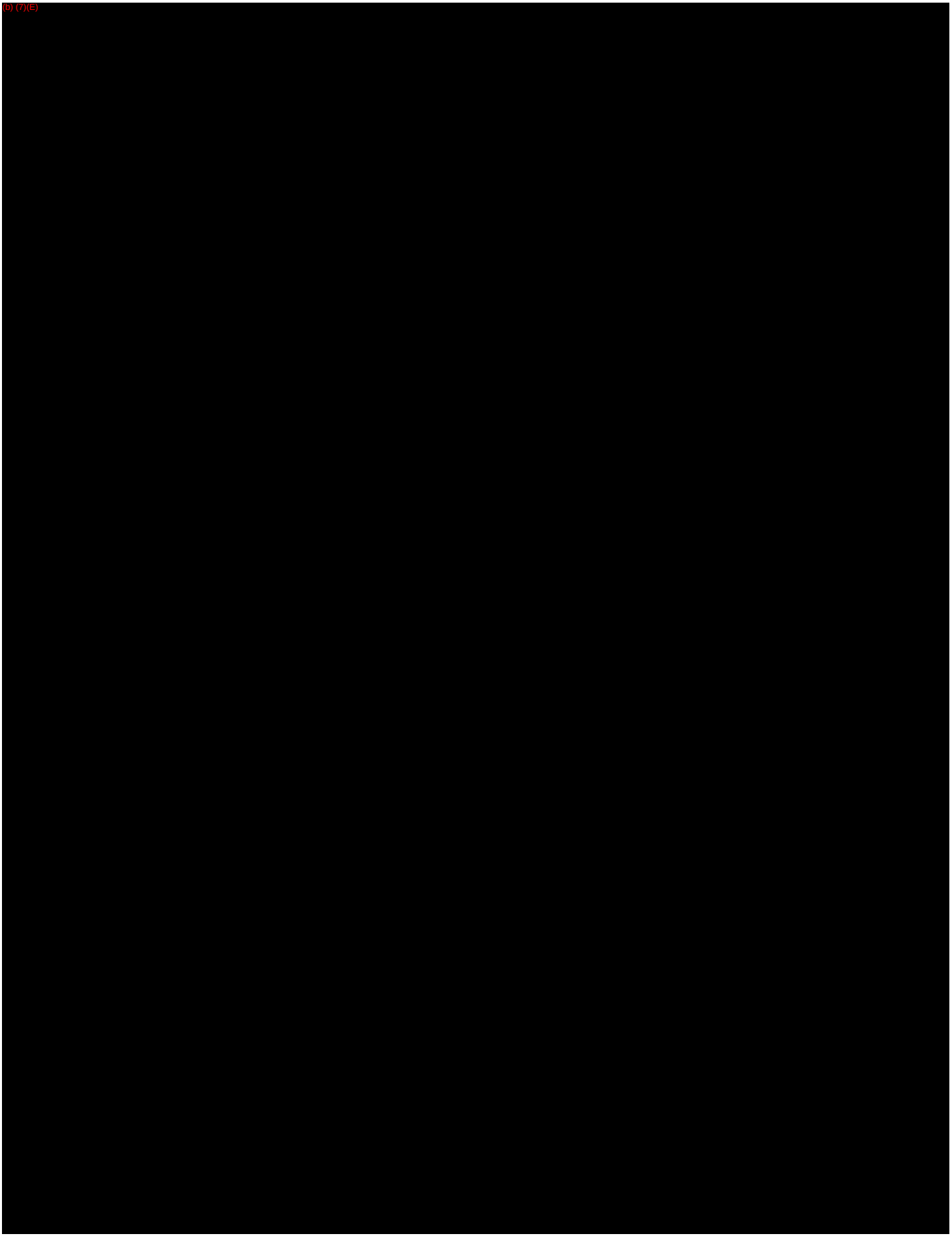
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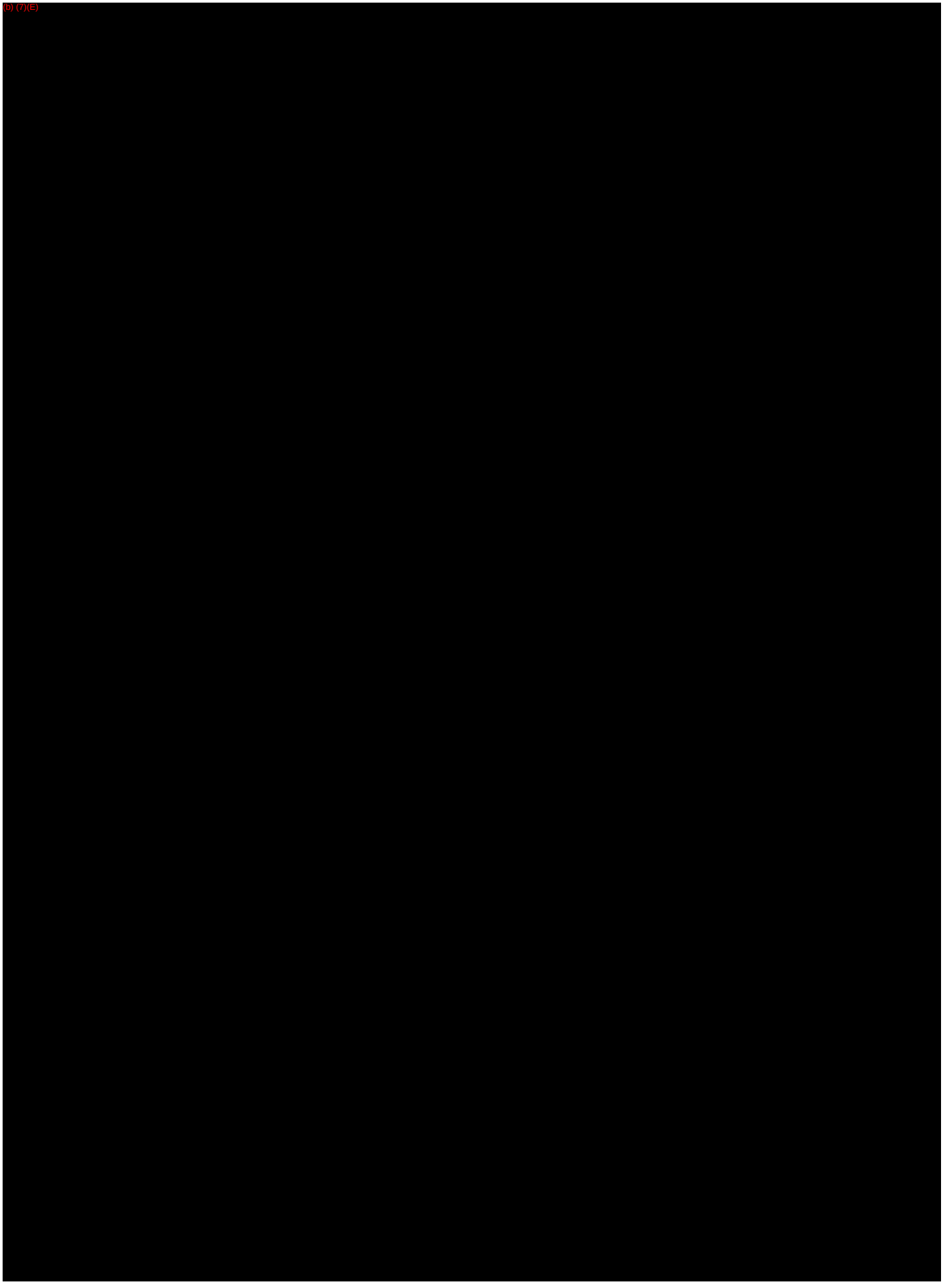
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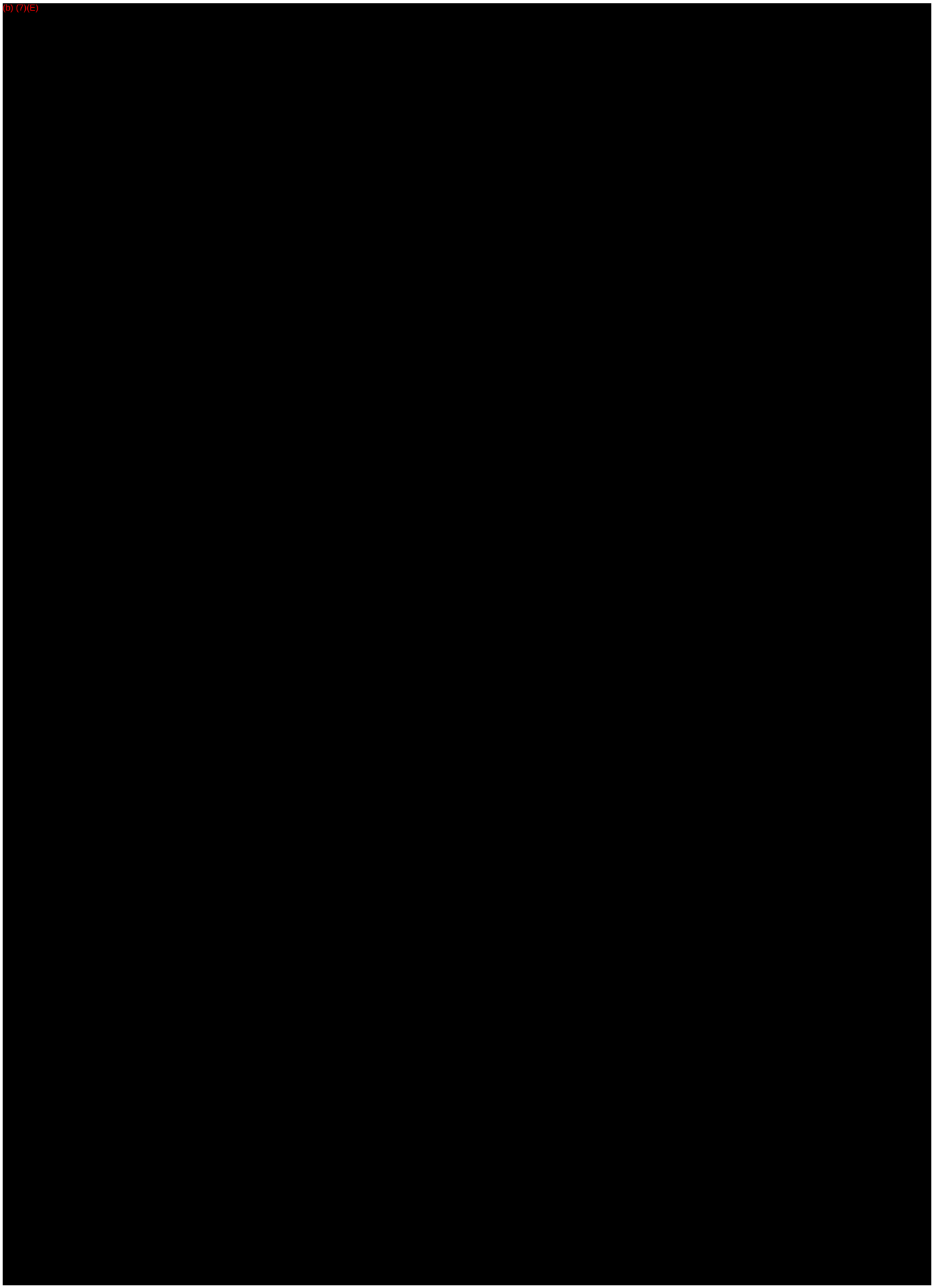
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References

Clinical Guide to Laboratory Tests, second edition. Norbert W. Tietz, ed., p 514, Saunders, 1990. Textbook of Clinical Chemistry. Norbert W. Tietz, ed., p 1299-1300, Saunders, 1986.

Federal Register: August 21, 2001 (Volume 66, Number 162), [Notices] Page 43876-43882.

ATAGO, Instructions of Urine Specific Gravity Refractometer – URICON-Ne.

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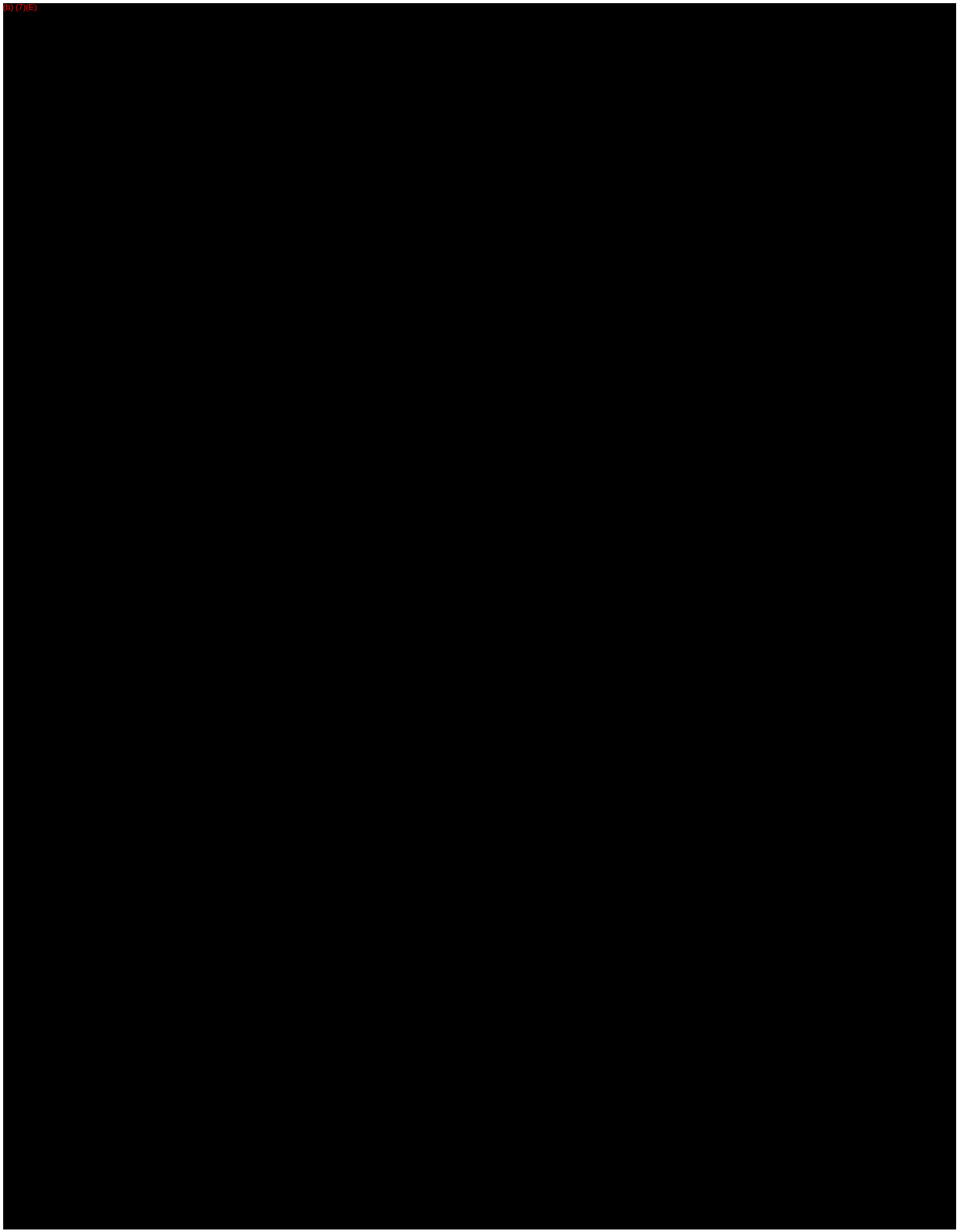
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OFFICE OF FORENSIC TOXICOLOGY SERVICES

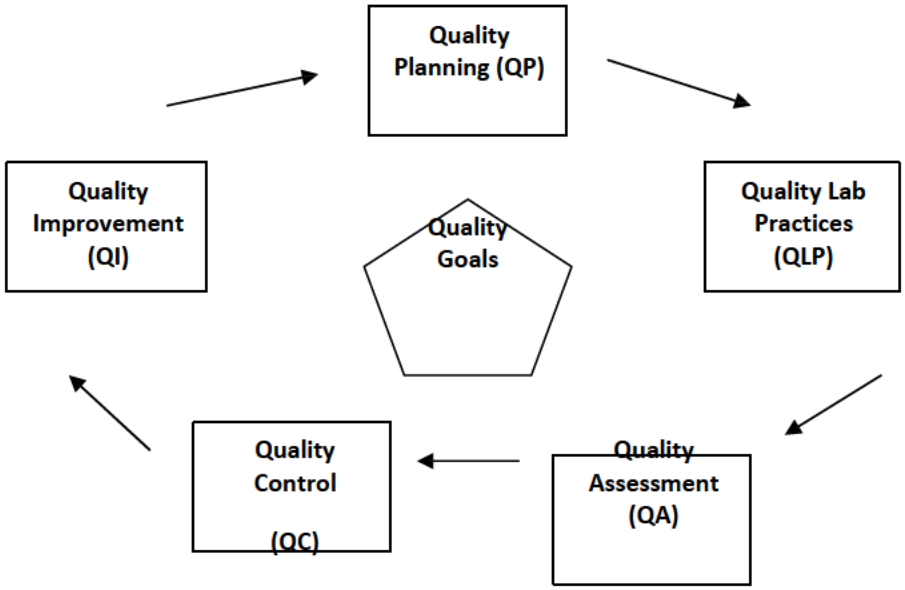
CHAPTER THREE

TOTAL QUALITY MANAGEMENT (QUALITY ASSURANCE and QUALITY CONTROL)

TOTAL QUALITY MANAGEMENT

Total quality management (TQM) is a comprehensive approach to producing data of sufficient quality to meet the needs of the customer. Quality assurance is the outcome of this whole quality management process, rather than being a component in the process. The components of TQM are illustrated in the figure below. Quality goals, determining the needs of the customer is critical to the process. How accurate and precise does the laboratory data need to be? Reproducibility is another factor. The 10% limits on repeat analyses ensure the reported results are not due to random error. Quality planning involves determining what instrumentation and reagents to use; what the educational background and training of the technologists performing the analysis needs to be; how data systems will record and transmit results; and what quality controls and proficiency tests will be in place. As these questions are answered quality laboratory practices are developed. Quality Laboratory Practices (QLP) refers to the policies, procedures, personnel standards, and physical resources that determine how work gets done in the laboratory. Quality laboratory practices are designed to facilitate achieving goals by minimizing the chance of making a significant error during the daily testing process.

Components of Total Quality Management (Overview)



A. Quality planning (QP)
B. Quality laboratory practices (QLP)
C. Quality assurance (QA)
D. Quality control (QC)
E. Quality improvement (QI)

QUALITY ASSURANCE

PSA Policy Statement
The D.C. Pretrial Services Agency is committed to formulating recommendations to promote the use of non-financial pretrial release under the least restrictive conditions and providing effective community supervision for individuals accused of criminal behavior in a manner that: (1) honors the constitutional presumption of innocence; (2) assists the judiciary to insure that the individual will return to court and will not be a danger to the community while on pretrial release; and (3) seeks to address the concomitant social problems of persons under criminal justice supervision - most notably, substance abuse – which substantially contributes to criminal behavior.

OFTS Mission Statement:
The mission of the Forensic Toxicology Drug Testing Laboratory is to serve and support the mission of the D.C. Pretrial Services Agency and Court Services and Supervision Agency for the District of Columbia:

- By providing laboratory data that is timely, scientifically correct and forensically sound
- By providing scientific and forensic information thorough scientific presentations and discussions to D.C. Pretrial Services Agency and Court Services and Supervision Agency for the District of Columbia.
- By providing expert testimony in forensic toxicology at judiciary proceedings
- Maintaining a professional ethical practice in forensic toxicology.

Introduction
OFTS has established a quality system with the continuing confidence that laboratory data is accurate, impartial, and relevant.

It is imperative that all work conducted by OFTS be of the highest quality possible while congruent with the needs of the D.C. Pretrial Services Agency (PSA) and Court Services and Supervision Agency for the District of Columbia (CSOSA) communities that it serves. This applies to the actual technical laboratory work performed, written reports, and courtroom testimony provided by the toxicologist/ chemist.

Technical competency can be achieved only by the combination of a number of components such as initial training, experience, continuing education through professional development, proficiency testing, and an appreciation of the scientific protocol/ methodology, all of which must be projected against a background of a proper professional ethic. Each component is important and overlaps the others. One cannot embrace a single component of quality assurance and disregard all others. Quality assurance does not, and cannot, rest on a single component.

Forensic work does not permit the rationalization of substandard work. It is widely expected that all work be exemplary and meet judicial and scientific scrutiny.

Quality assurance is, and must be, a dynamic endeavor; it is both all encompassing and never-ending. Determining and improving the quality of the laboratory's analytical data by controlling the identifiable and measurable factors that affect the data is a primary goal of a quality assurance program.

Goals and Objectives

The goal of this Quality Assurance Program is to deliver in a timely manner defect-free service to our users by adherence to documented requirements that fully satisfy the highest degree of scientific and legal credibility. This may be accomplished by meeting the more specific goals addressed in the Quality Assurance Program elements:

The objectives of the Quality Assurance Program shall be supported and understood by The Staff of the OFTS.

Definitions

Quality Assurance (QA): A separate function that utilizes verifications and audits to evaluate and oversee the quality control functions.

Quality Control (QC): Those techniques and activities, which insure that the quality of a product or service is maintained and will meet and satisfy, specified criteria.

Responsibility for the Quality Assurance Program

The success of any quality assurance program is based on the participation, input and support of all laboratory personnel. A commitment to the quality assurance goals of the organization is essential. The cooperative effort of the entire staff is necessary to achieve the established standards of quality for the lab. The requirements and standard set by the OFTS Quality Assurance Team must be understood and strictly adhered to by all employees.

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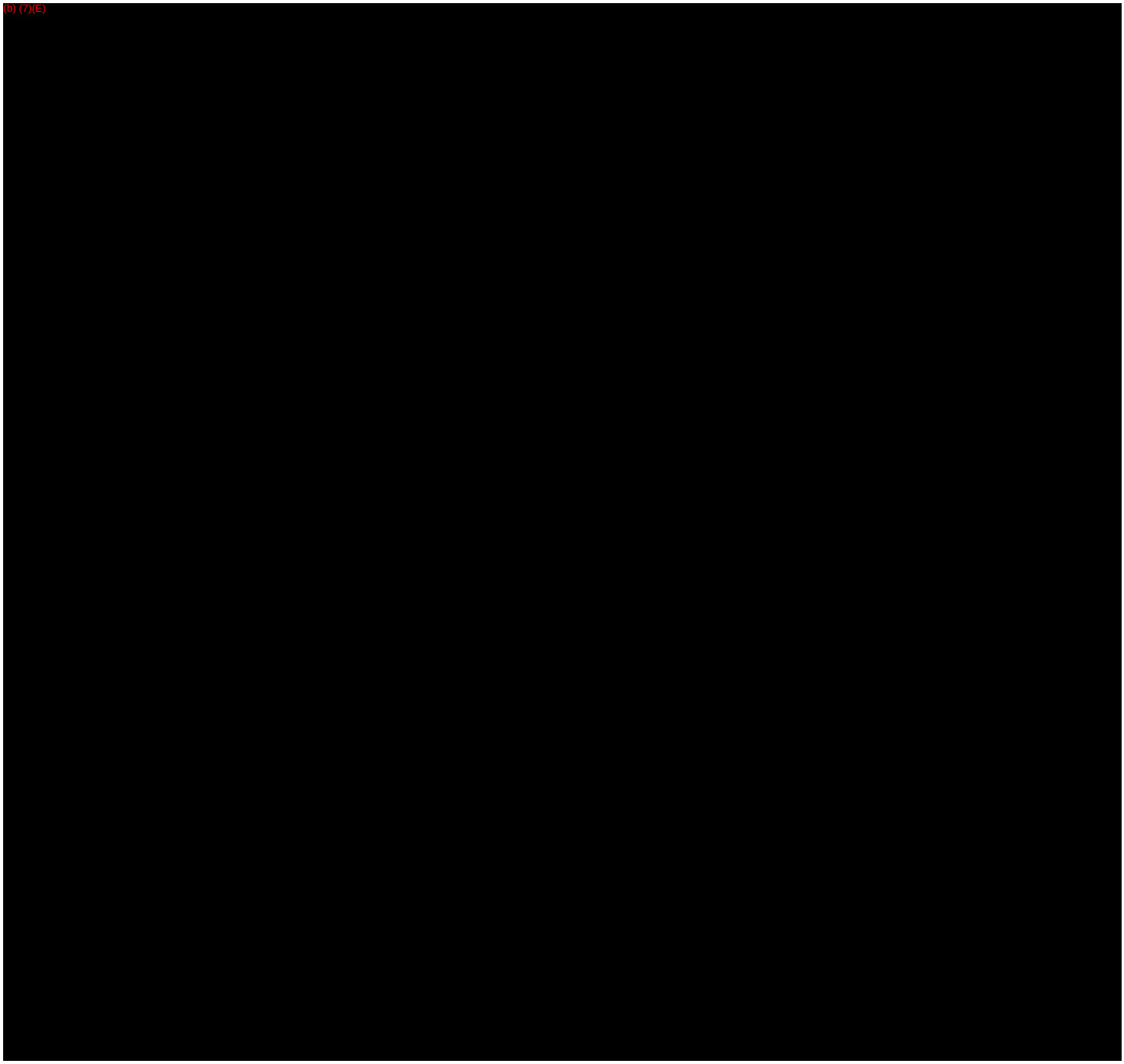

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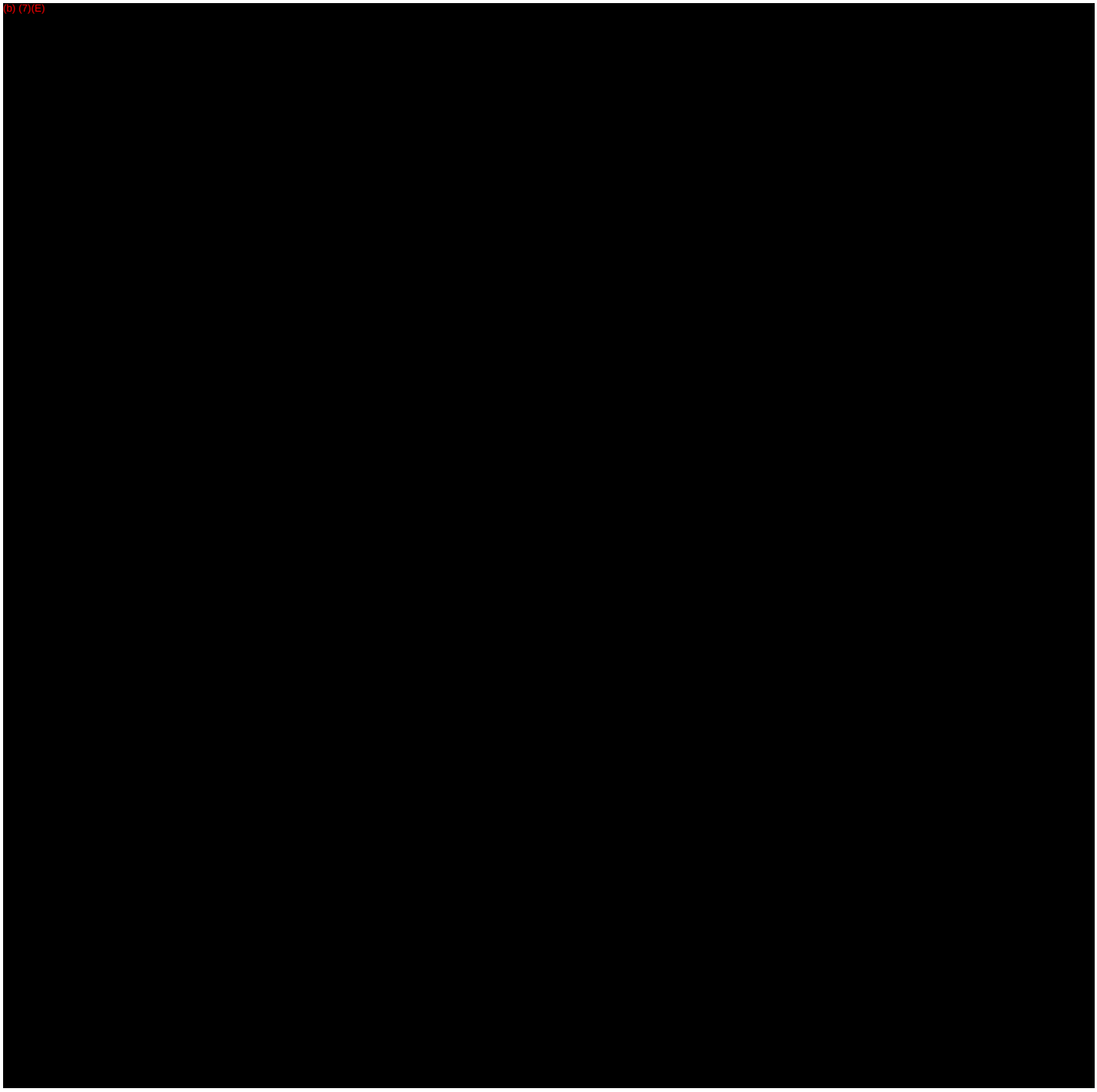

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QUALITY CONTROL

Quality control is the metric of TQM. Quality Control refers to procedures for monitoring the work processes, detecting problems, and making corrections prior to delivery of products or services. Quality control starts with selecting appropriate control materials. Based on the stability and precision of the analytical method, the number and frequency of controls run can be determined. Quality control then applies statistical tests to detect changes that may exceed the quality requirements of the analytical process. Quality control rules determine the response when the process is in or out of control.

The purpose of quality control is to detect changes in the analytical process that would produce errors of significant magnitude that the unknown test results will not meet the customer's needs. The quality control program is not only the testing of a material of known composition and concentration but includes statistical analysis of the data and application of quality control rules to ensure that consistently precise and accurate data have been produced. To be effective, the quality control program must alert the technologist when something is wrong and provide a framework to remedy the problem in a timely manner.

Quality control materials are tested in the same way as the unknown specimens. The quality control material should be of the same matrix as the unknowns and be at concentrations sufficient to detect significant error at the decision point, the positive - negative cut-off point.

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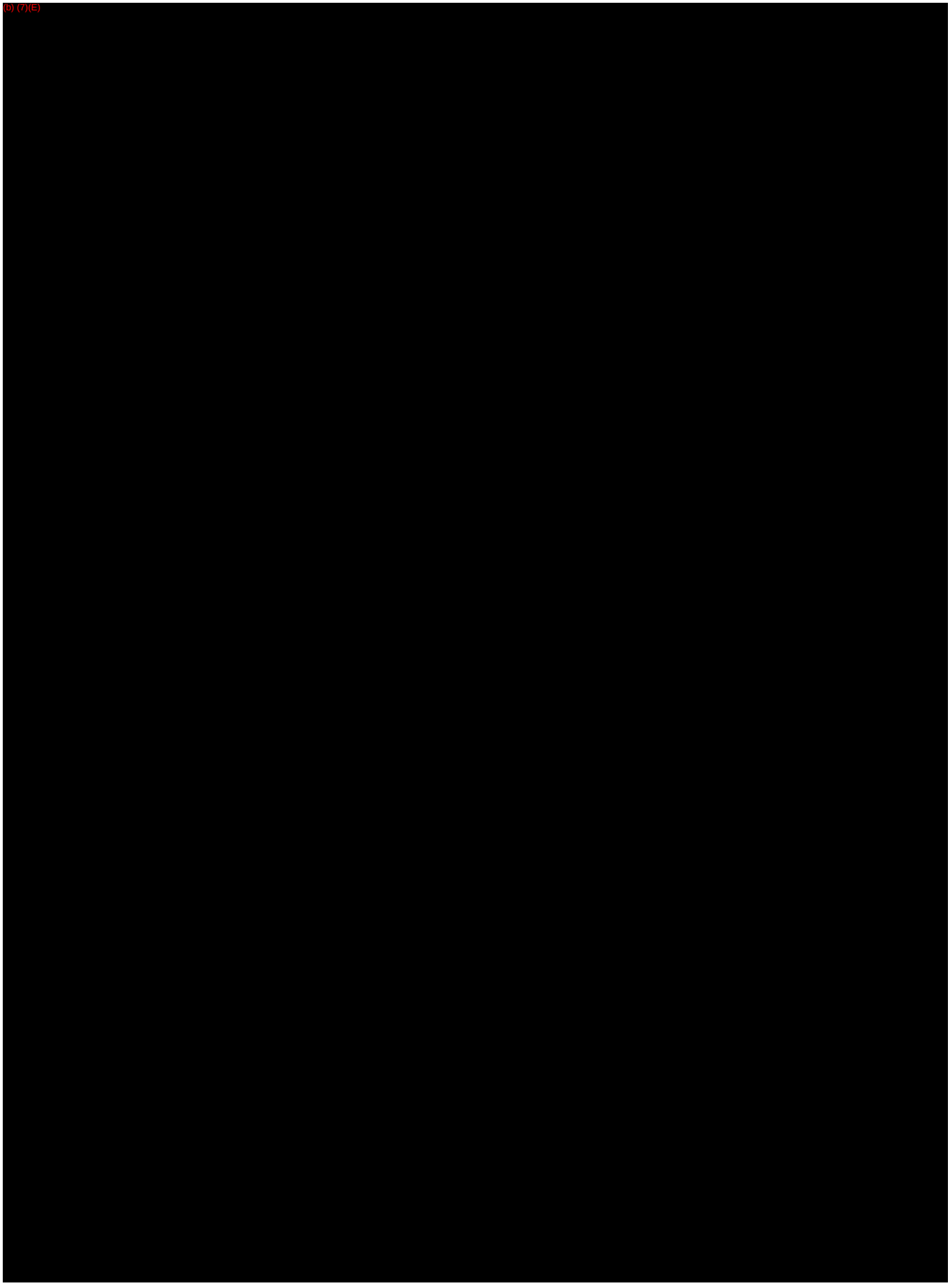

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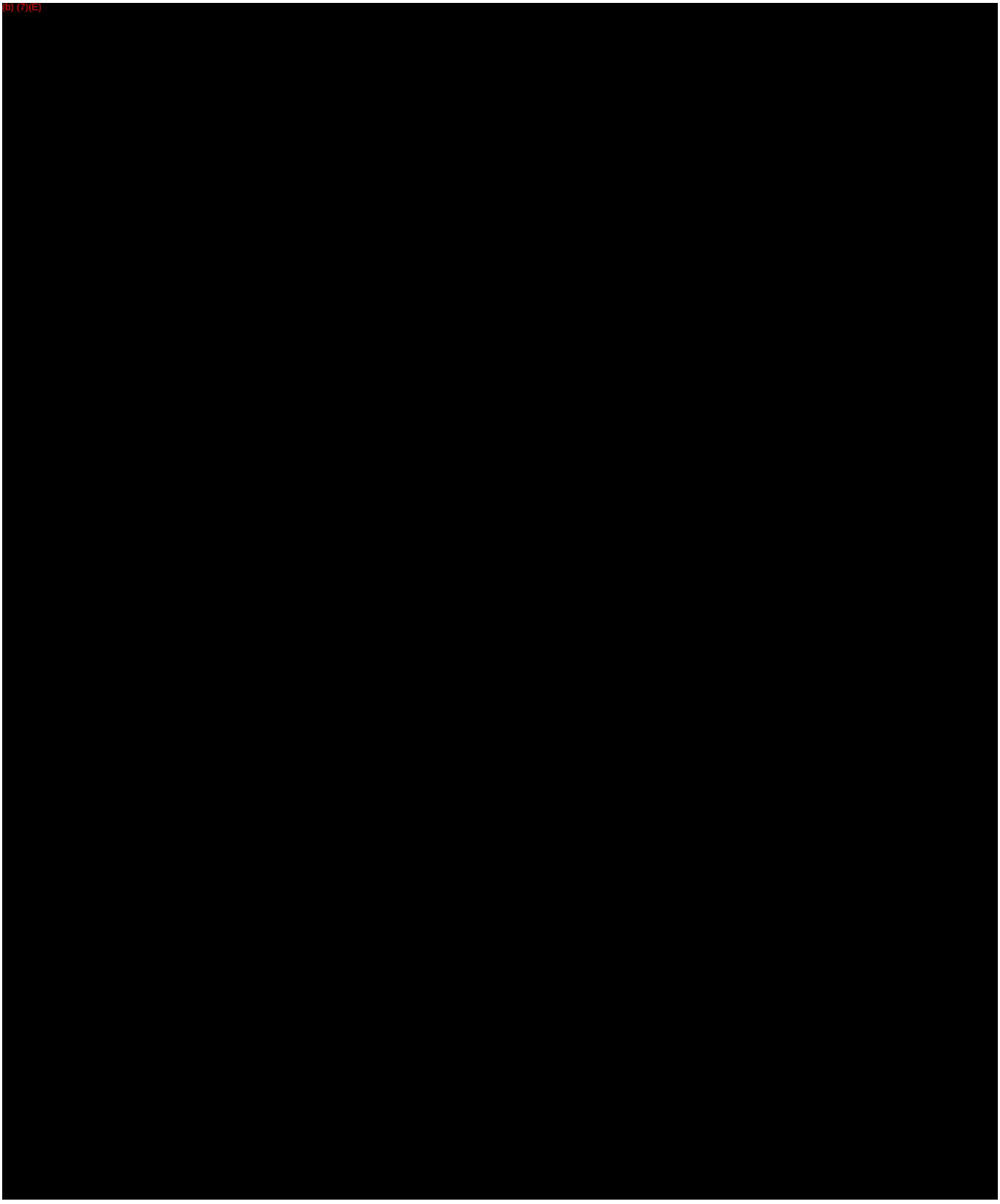


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References

Accreditation Manual", American Society of Crime Laboratory Directors/Laboratory Accreditation Board, 1997.

Garfield, Frederick M., Quality Assurance Principles for Analytical Laboratories, Associations of Official Analytical Chemists, 1991 (1984).

"Quality Assurance and Proficiency Testing in the Forensic Science Laboratory", Course Manual, American Academy of Forensic Sciences, February 1996.

"Minimum Requirements for a Water Quality Assurance Program", U.S. Environmental Protection Agency, Washington, D.C., 1976.

"Quality Assurance in Clinical Chemistry", Course Manual, U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, Atlanta, Georgia, 1979.

"Implementing Standardized Methods in the Forensic Science Laboratory", Course Manual, American Academy of Forensic Science, February 1998.

Westgard JO, Barry PL, Hunt MR, Groth T. A multi-rule Shewhart chart for quality control in clinical chemistry. Clin Chem 1981; 27:pp. 493-501.

Westgard JO, Barry PL. Improving Quality Control by use of Multirule Control Procedures. Chapter 4 in Cost-Effective Quality Control: Managing the quality and productivity of analytical processes. AACC Press, Washington DC 1986, pp. 92-117.

Westgard, JO, Klee GG. Quality Management. Chapter 16 in Fundamentals of Clinical Chemistry, 4th edition. Burtis C, ed., WB Saunders Company, Philadelphia, 1966, pp. 211-223.

Westgard Jo, Klee GG. Quality Management. Chapter 17 in Textbook of Clinical Chemistry, 2nd edition. Burtis C, ed., WB Saunders Company, Philadelphia, 1994, pp. 548-592.

Cembrowski GS, Sullivan AM. Quality Control and Statistics, Chapter 4 in Clinical Chemistry: Principles, Procedures, Correlations, 3rd edition. Bishop ML, ed., Lippincott, Philadelphia, 1996, pp. 61-96.

Cembrowski GS, Carey RN. Quality Control Procedures. Chapter 4 in Laboratory Quality Management. ASCP Press, Chicago 1989, pp. 59-79.

Westgard JO, Groth T, Aronsson T, Falk H, deVerdier C H. Performance characteristics of rules for internal quality control: Probabilities for false rejection and error detection. Clin Chem 1977;23:1857 67.

Westgard JO, Groth T. Power functions for statistical control rules. Clin Chem 1979;25: 863 69.

Westgard JO, Barry PL. Cost-Effective Quality Control: Managing the quality and productivity of analytical processes. AACC Press, Washington, DC, 240 p, 1986.

Westgard JO. Analytical quality assurance through process planning and quality control. Arch Pathol Lab Med 1992;116: 765-769

Westgard JO. A QC planning process for selecting and validating statistical QC procedures. Reviews in Clinical Biochemistry 1994;15(iv):155-64.

Westgard JO. Error budgets for quality management: Practical tools for planning and assuring the analytical quality of laboratory testing processes. Clin Lab.

Westgard JO. Internal quality control: planning and implementation strategies. Ann Clin Biochem 2003; 40:593-611.

Levey S, Jennings ER. The use of control charts in the clinical laboratory. Am J Clin Pathol 1950;20:1059-66.

OFFICE OF FORENSIC TOXICOLOGY SERVICES

CHAPTER FOUR

DTMS 3.0

OFTS' LABORATORY INFORMATION MANAGEMENT SYSTEM

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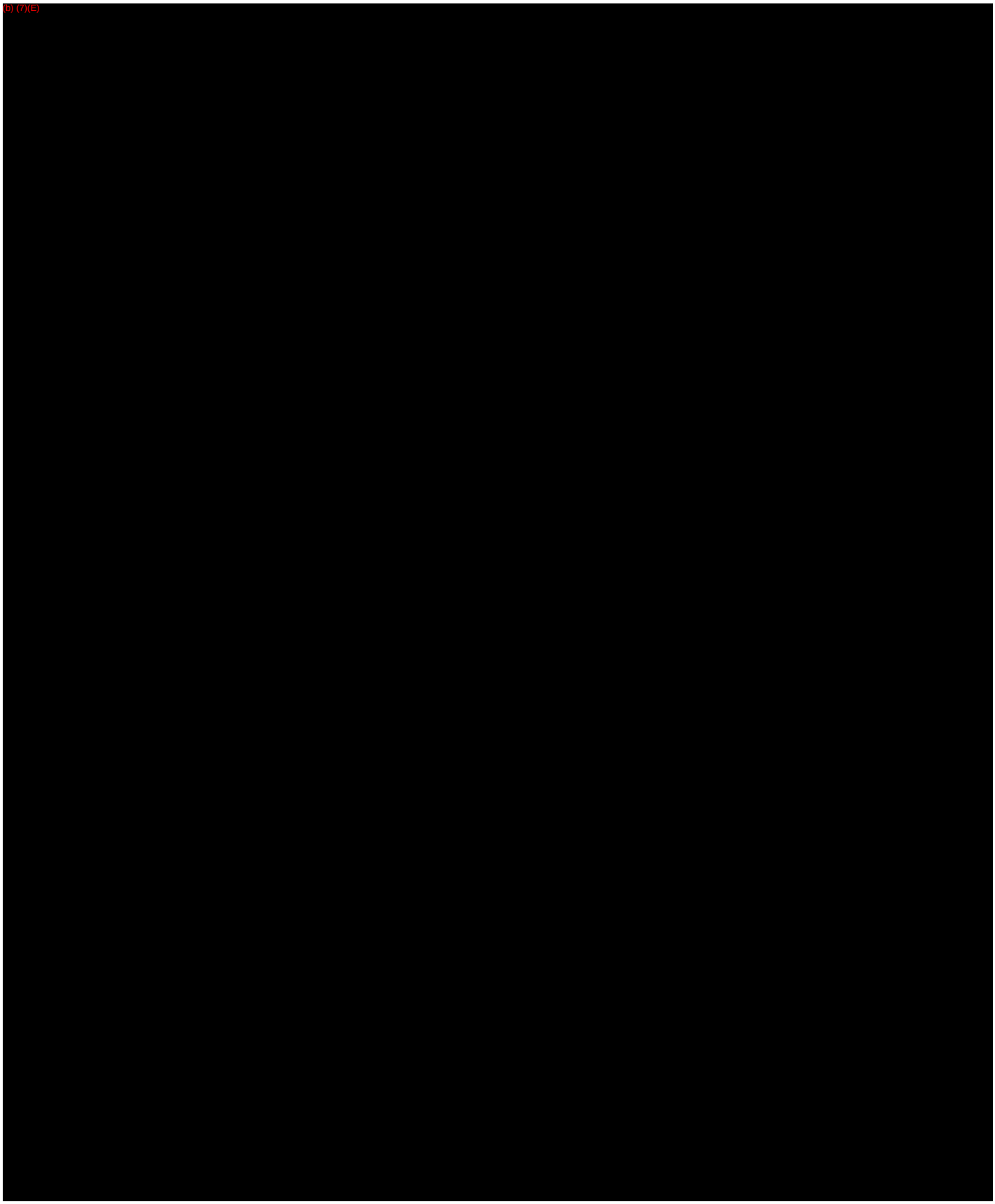


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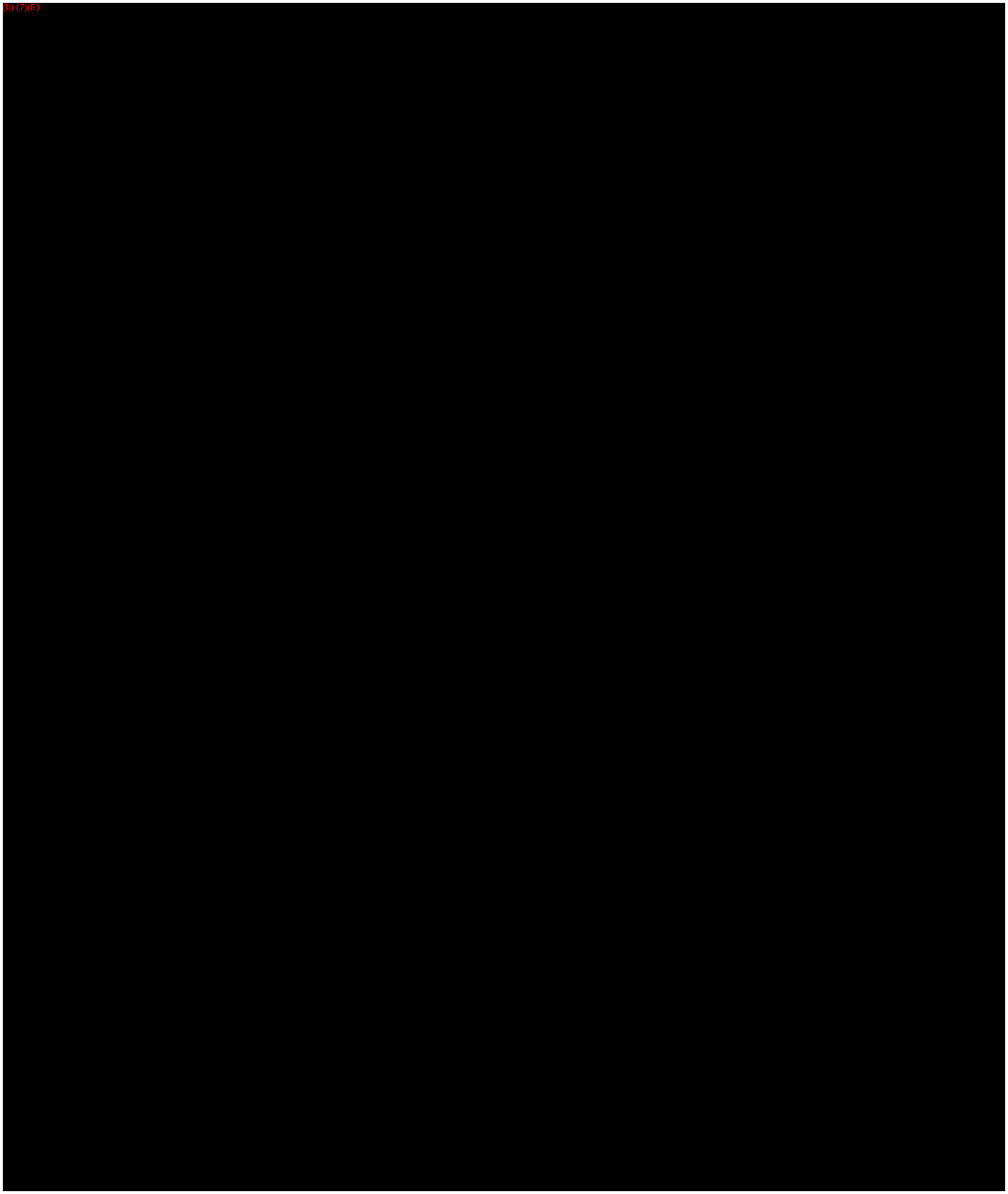

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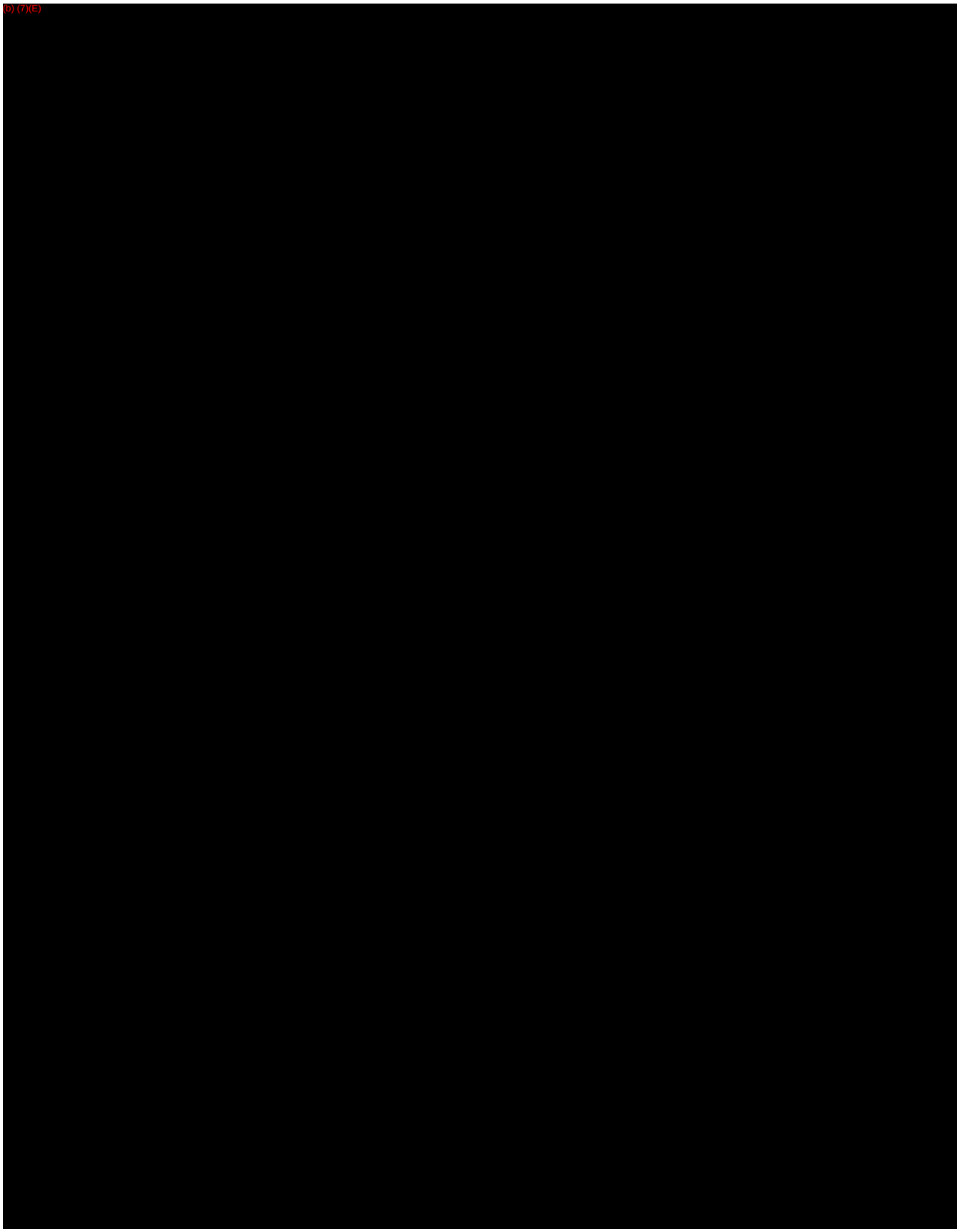

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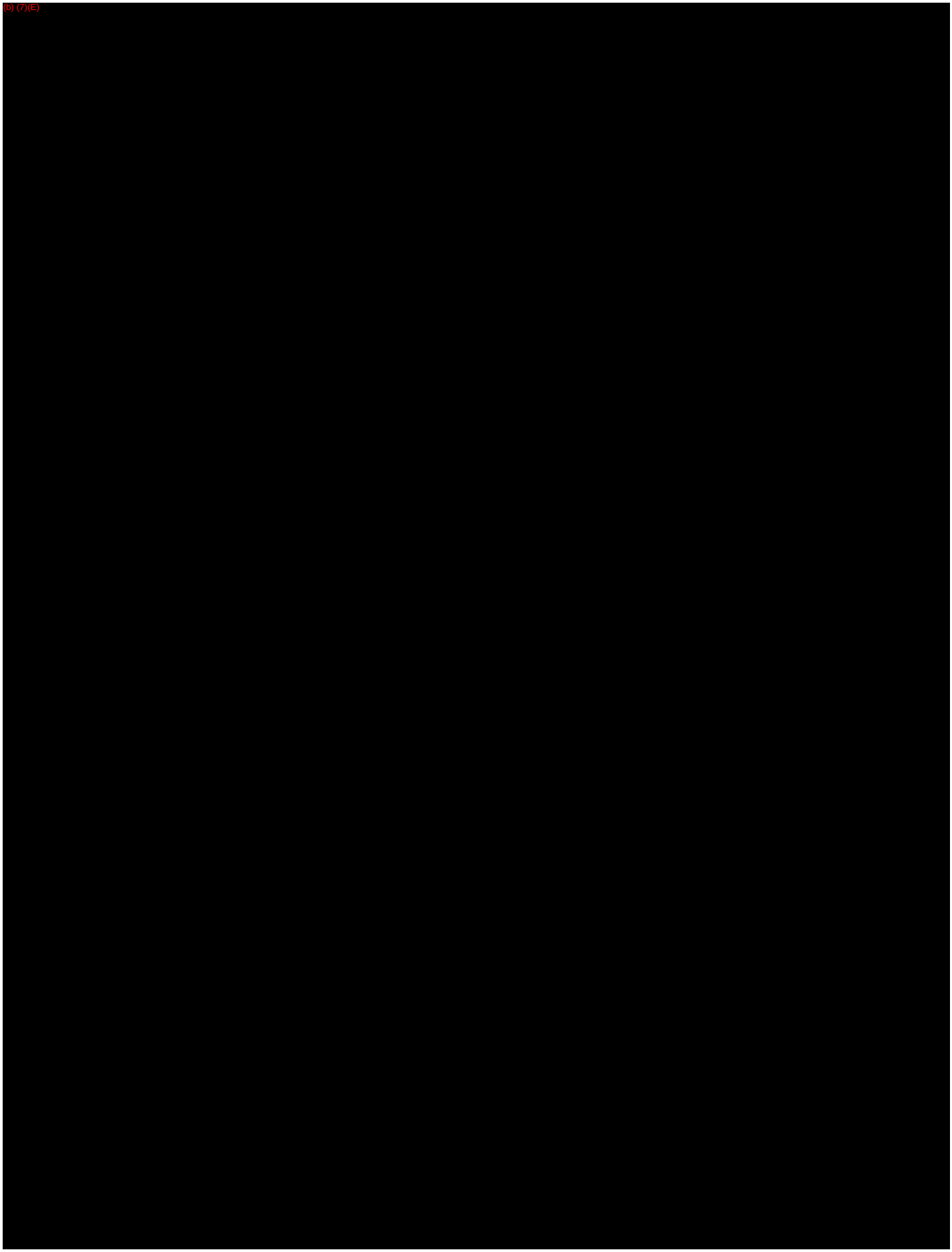

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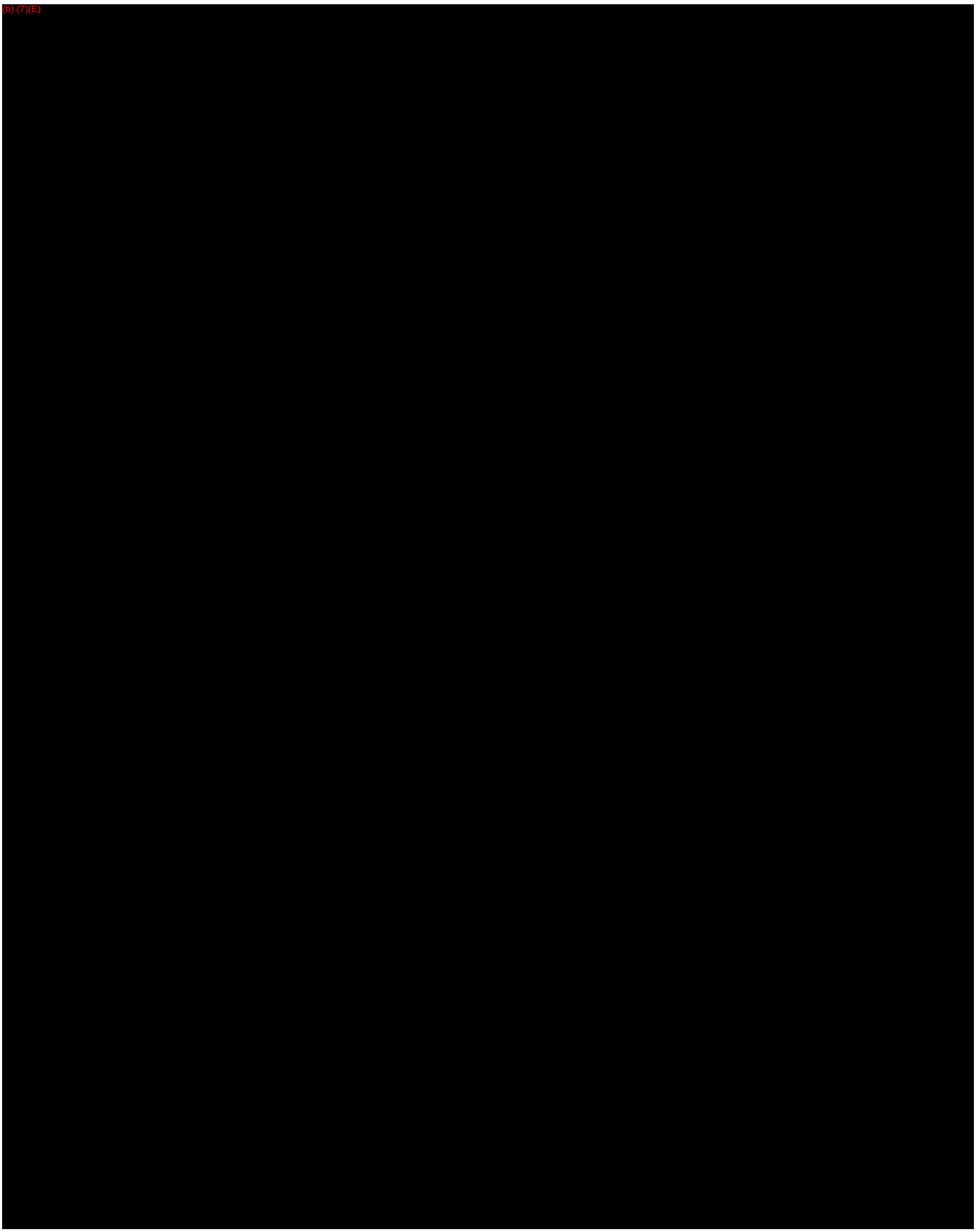

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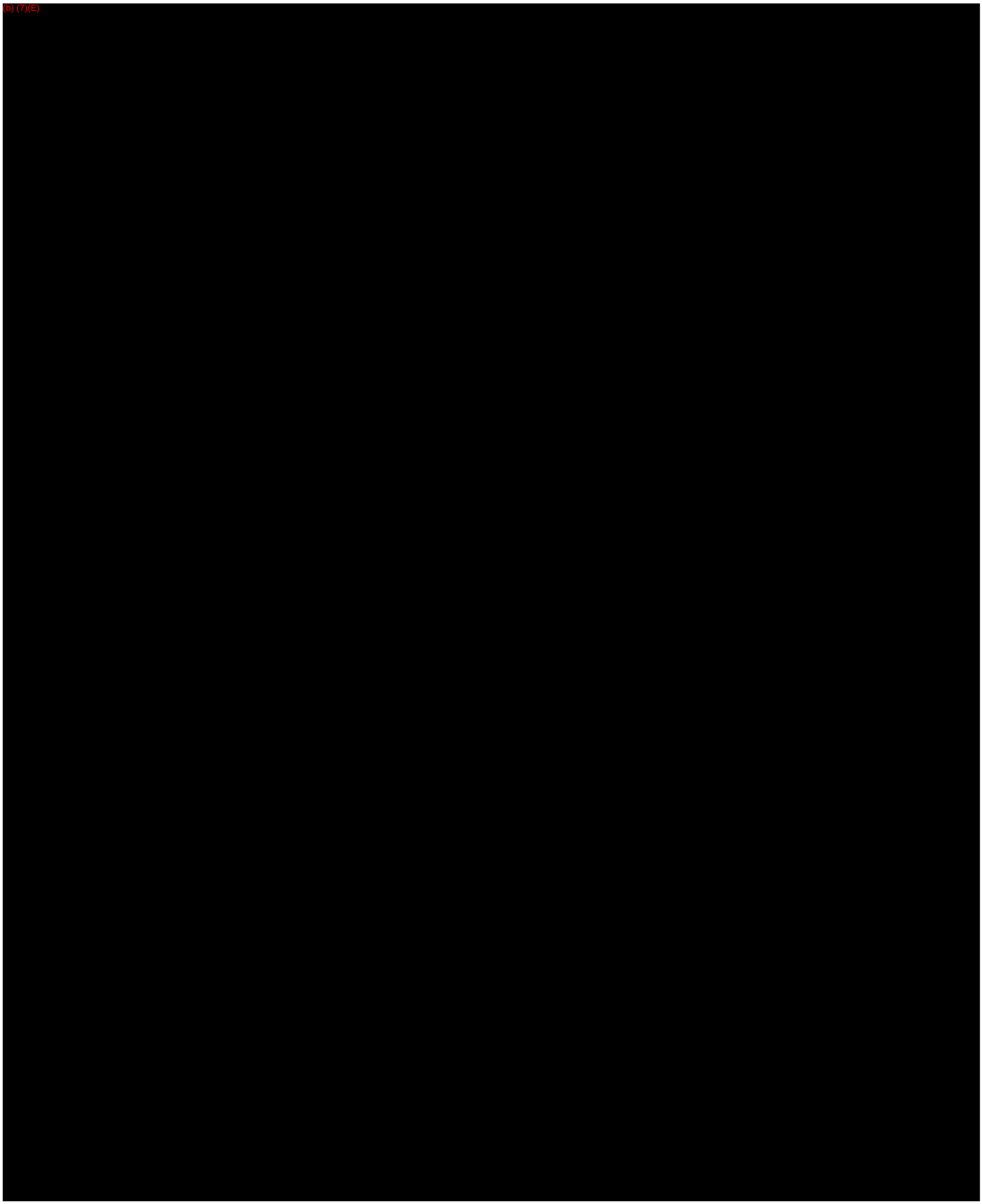

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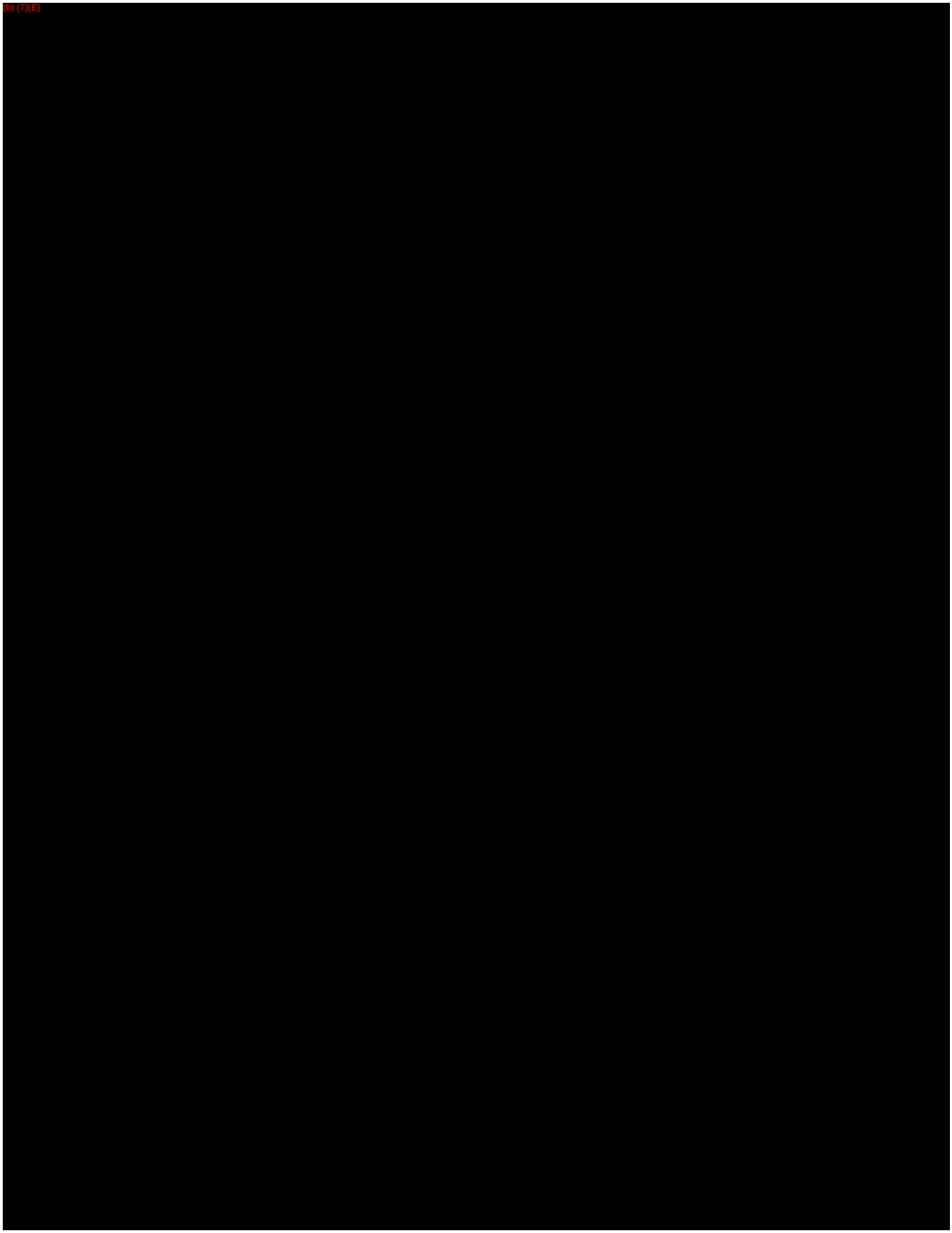
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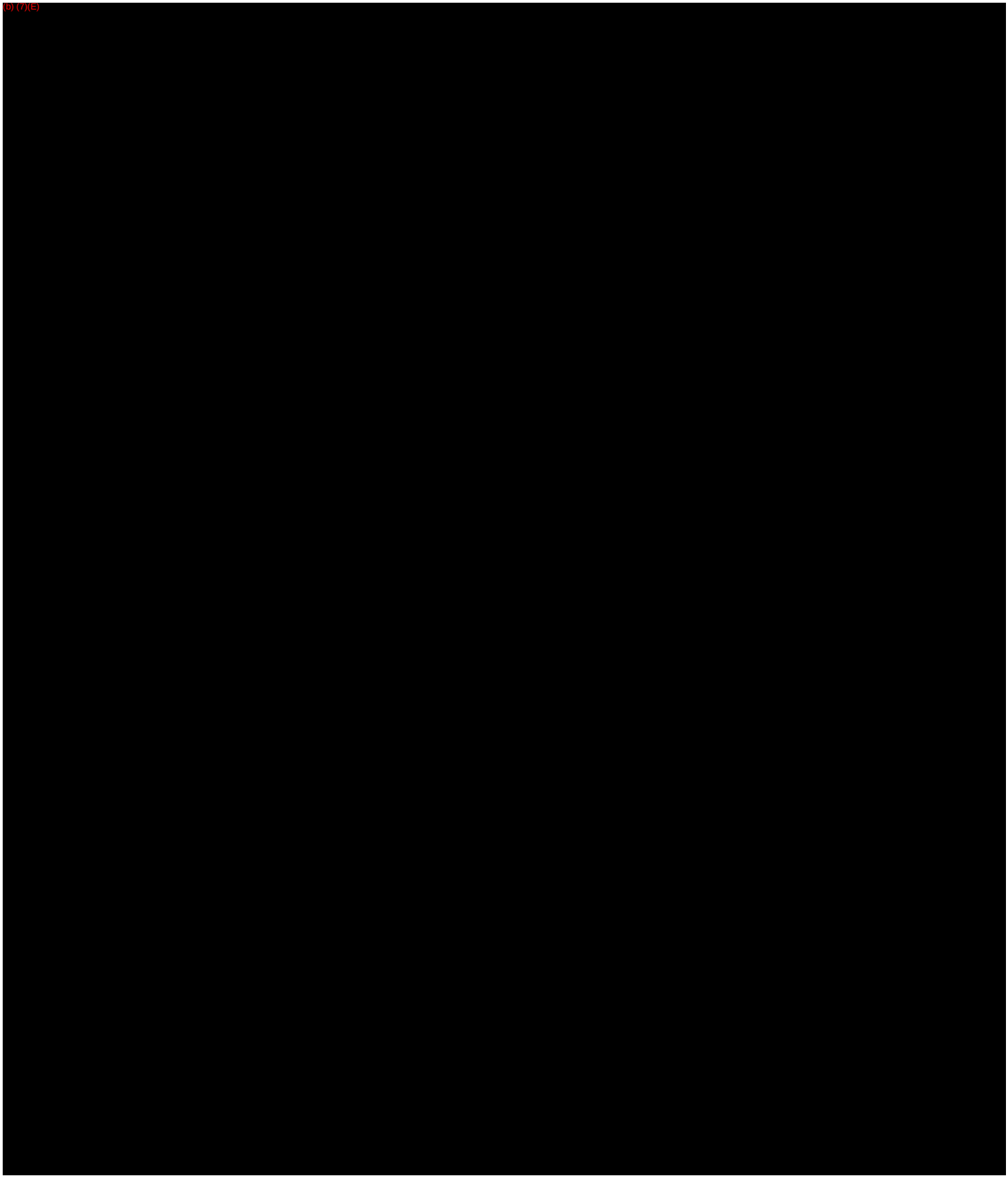


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OFFICE OF FORENSIC TOXICOLOGY SERVICES

CHAPTER FIVE

IMMUNOASSAY/SCREENING

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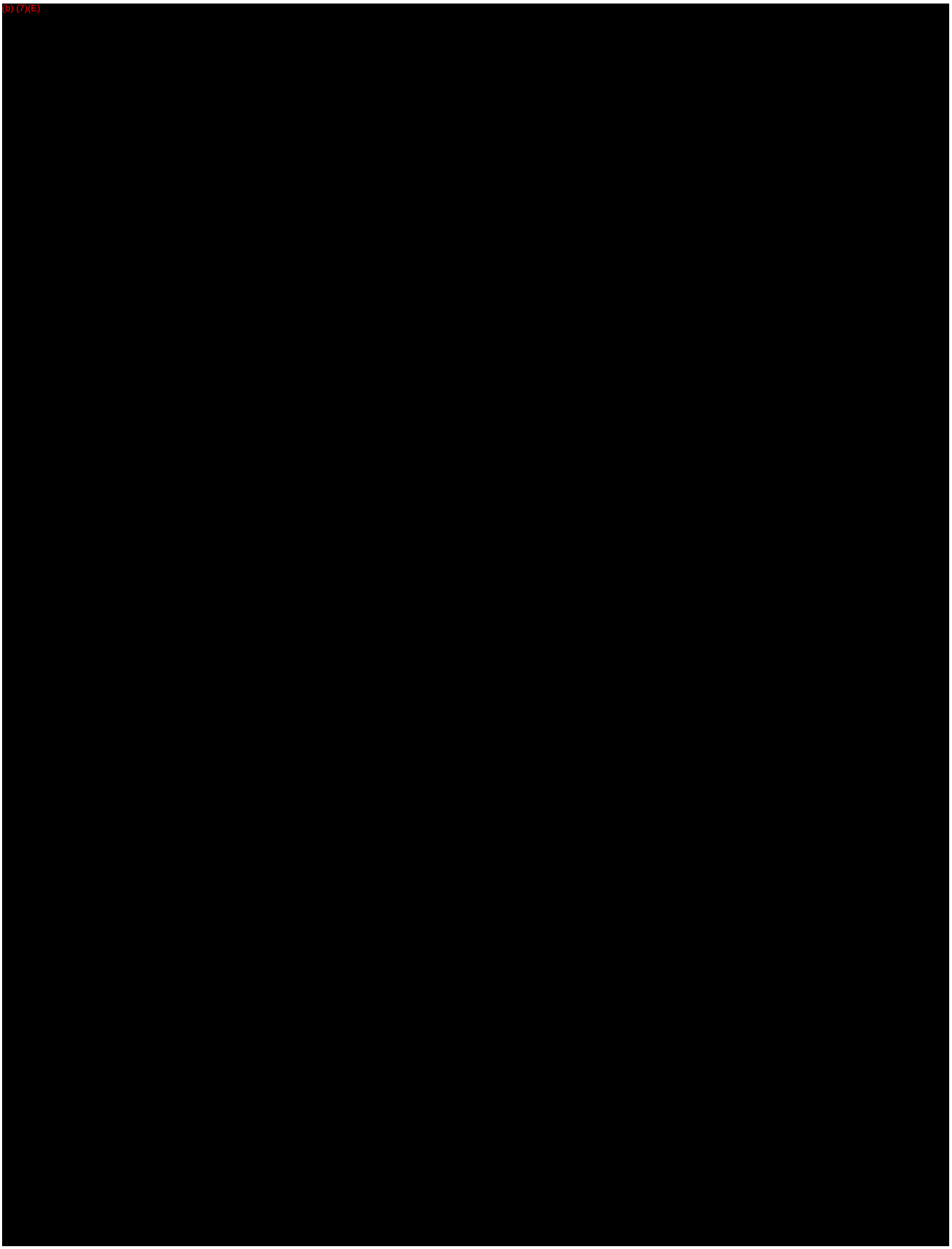

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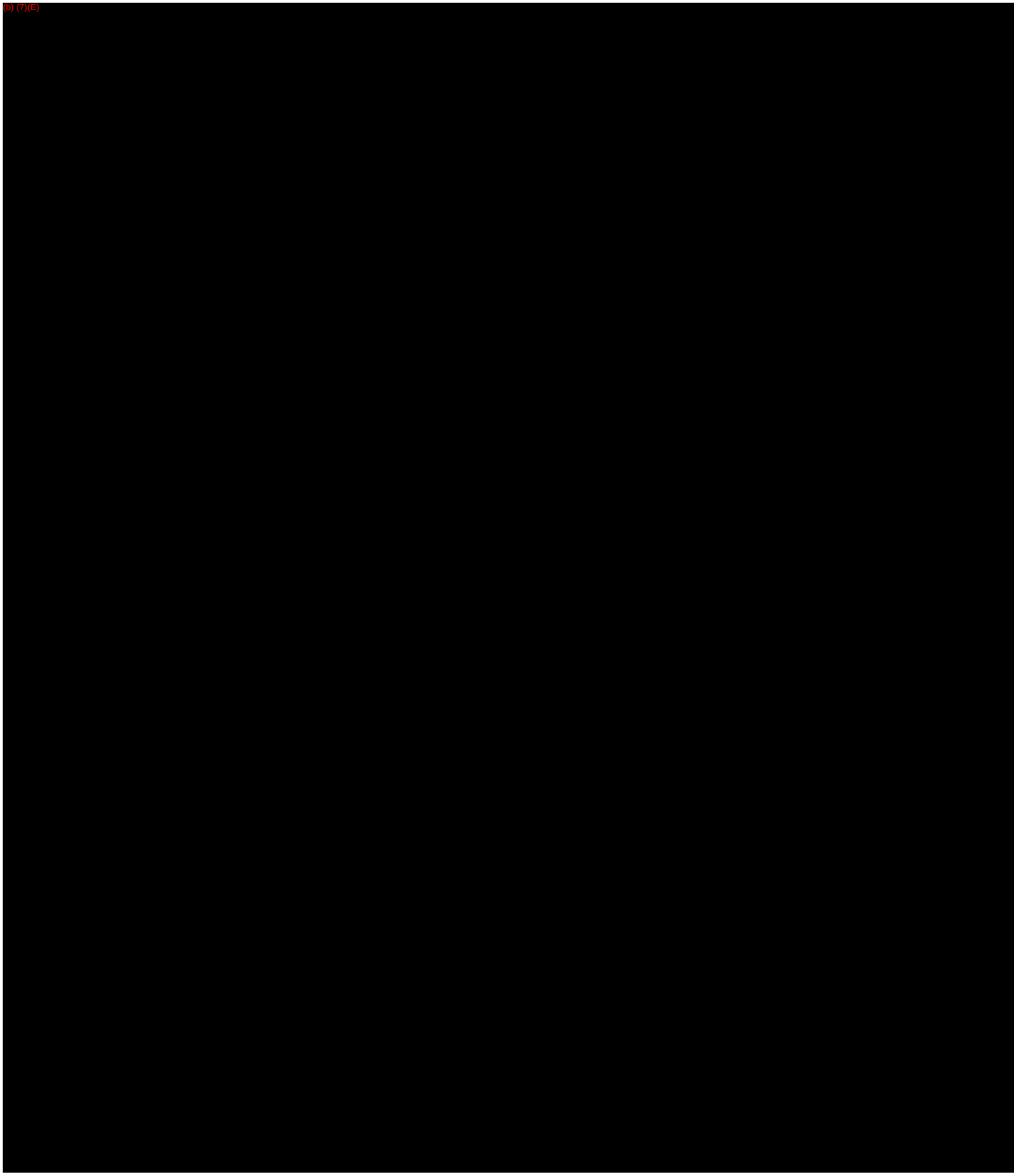

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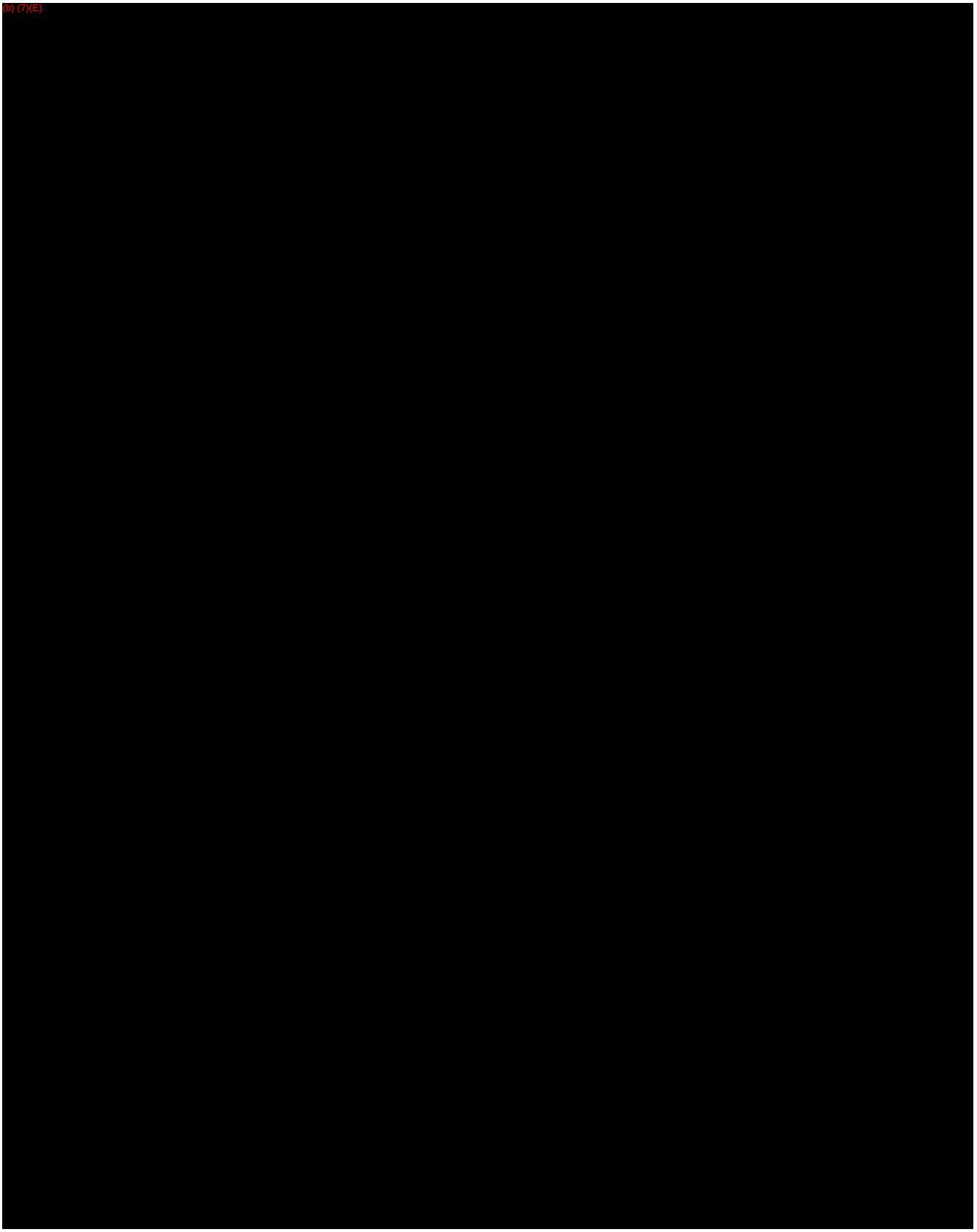

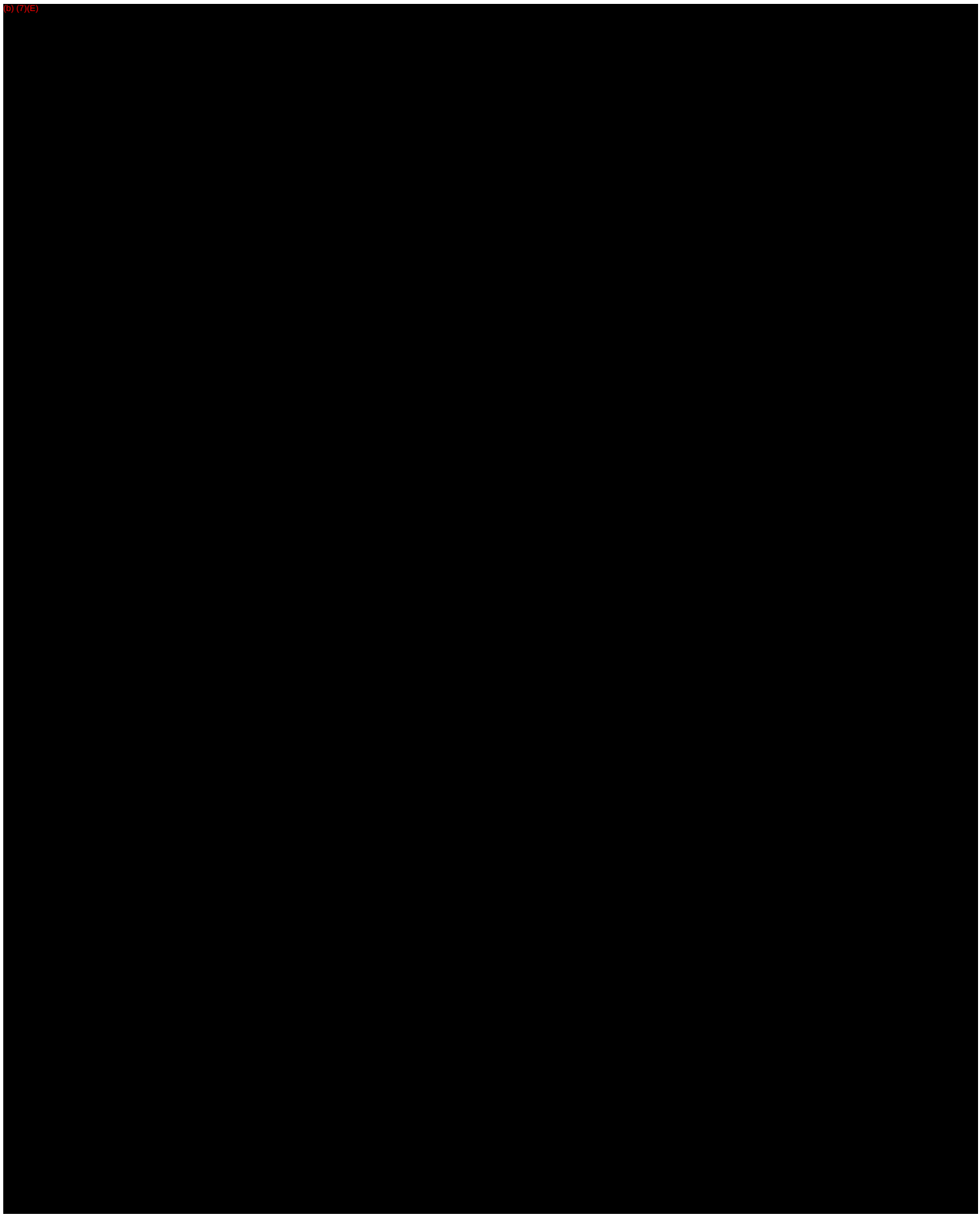
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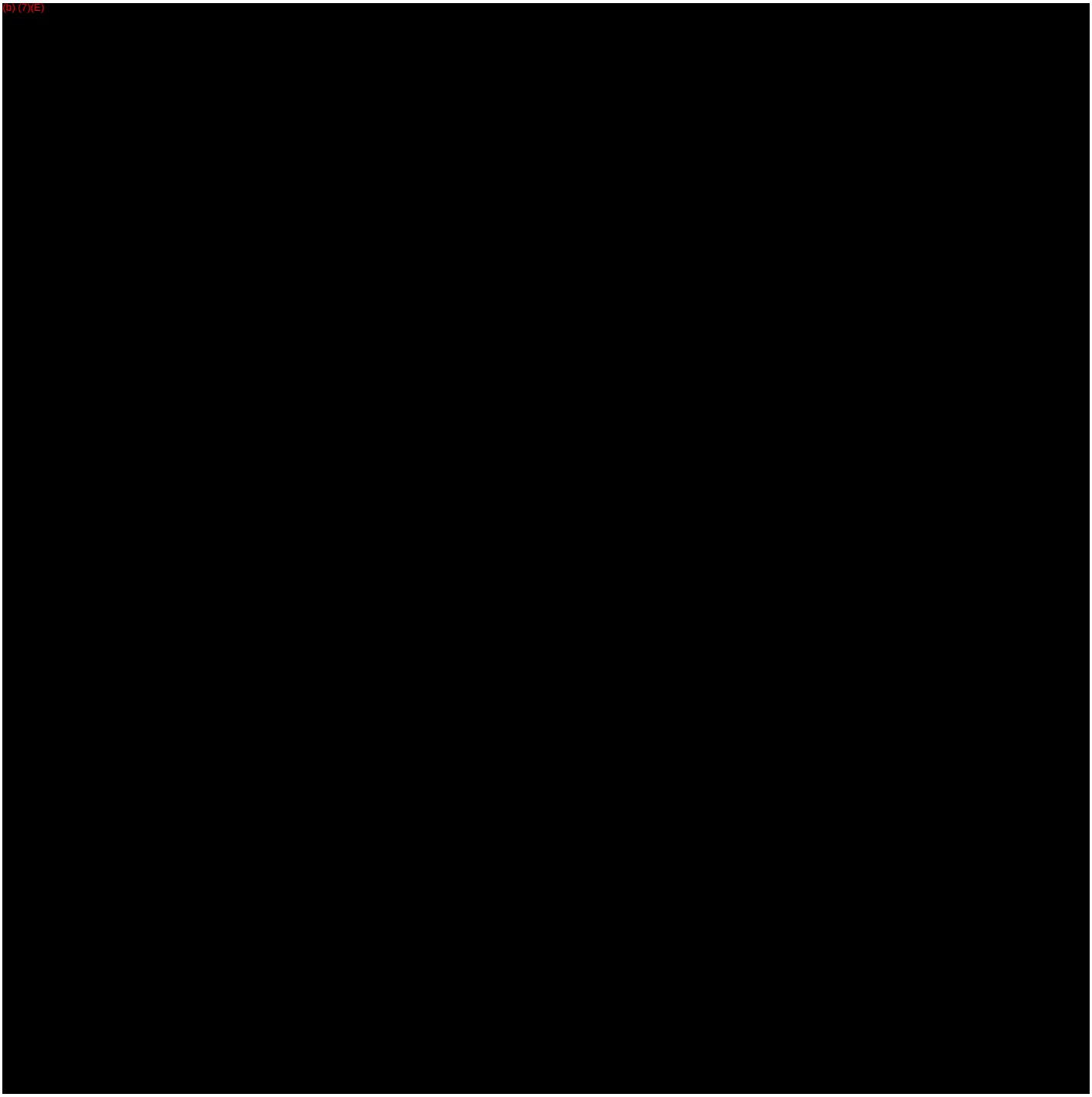

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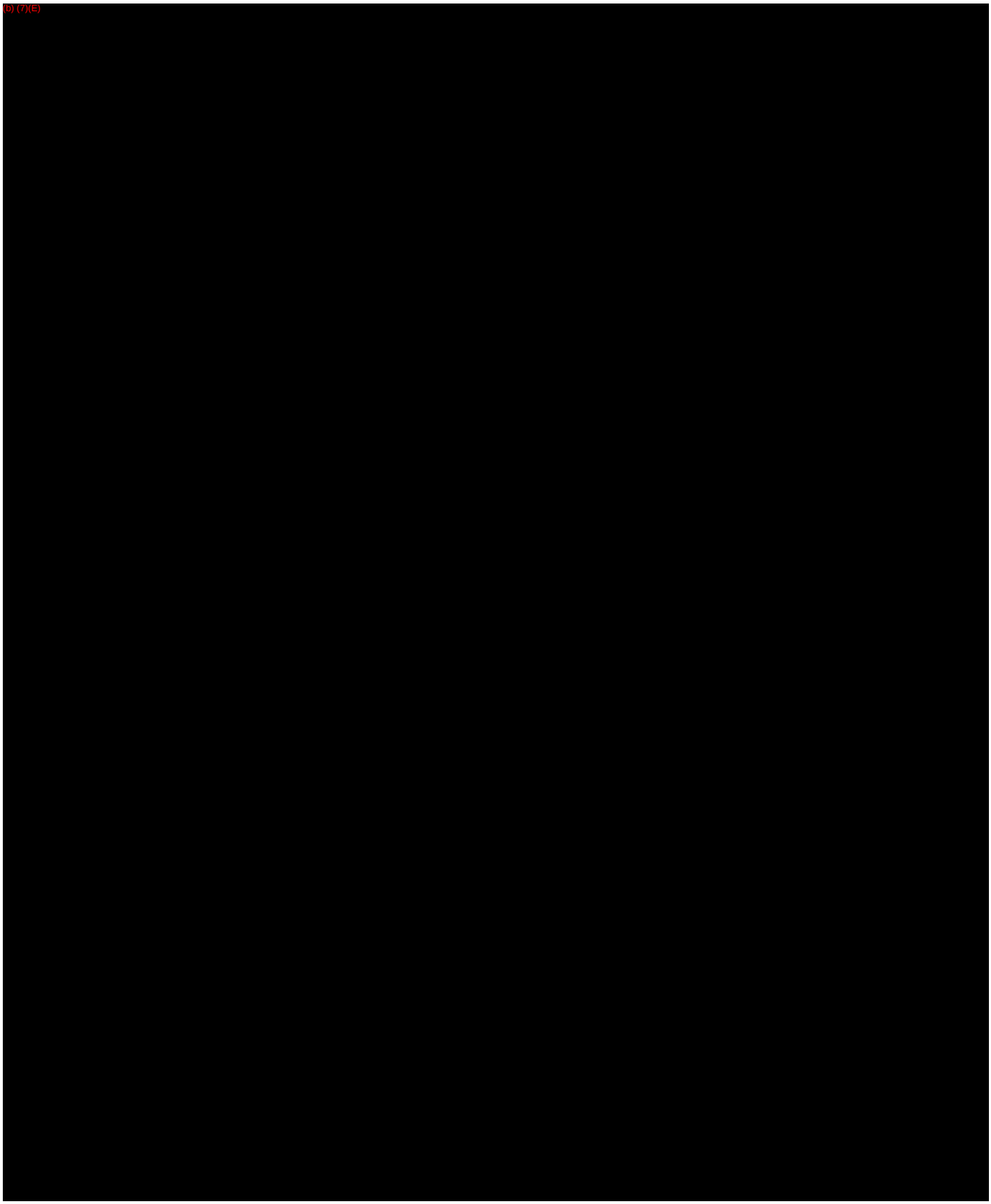

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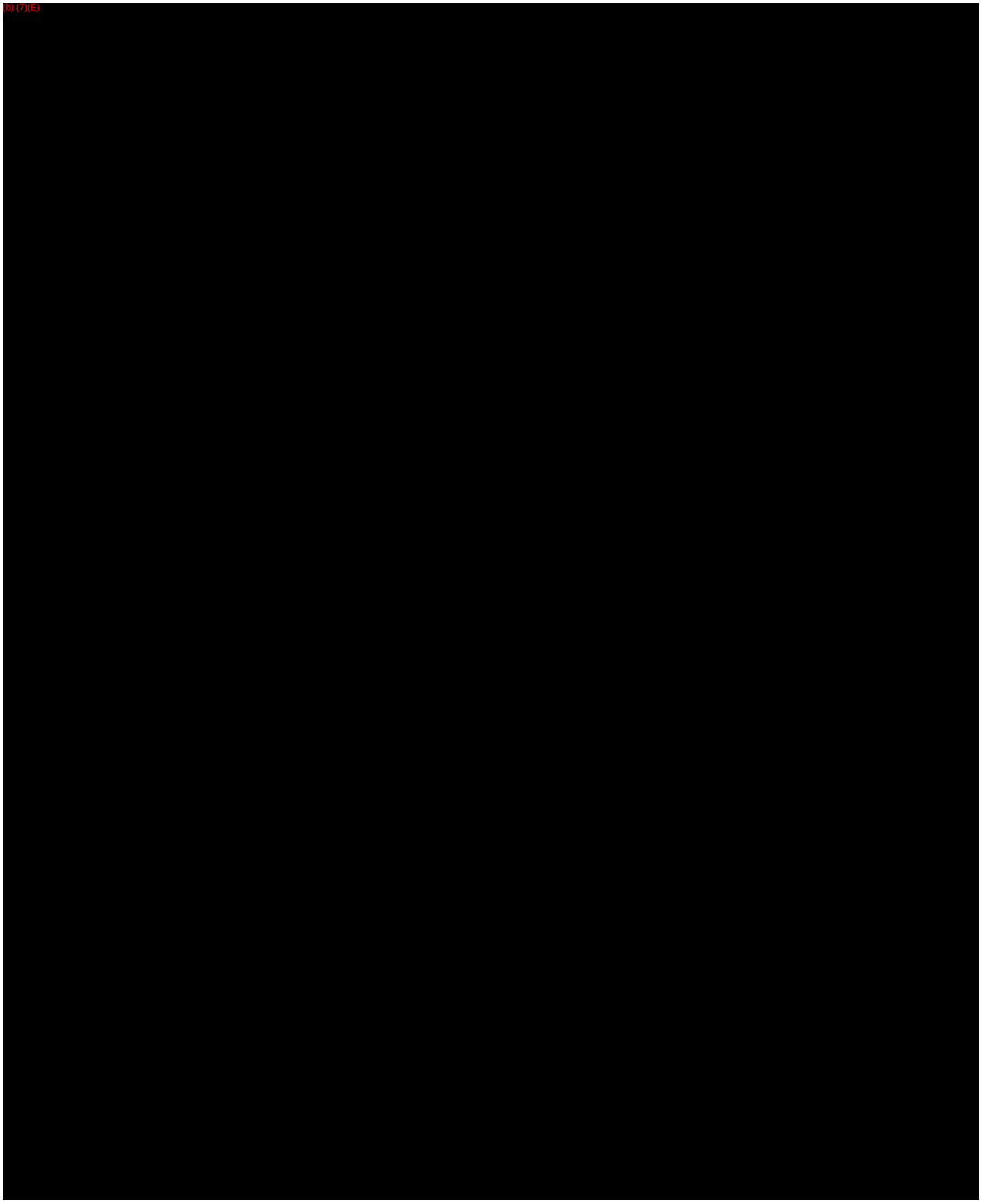

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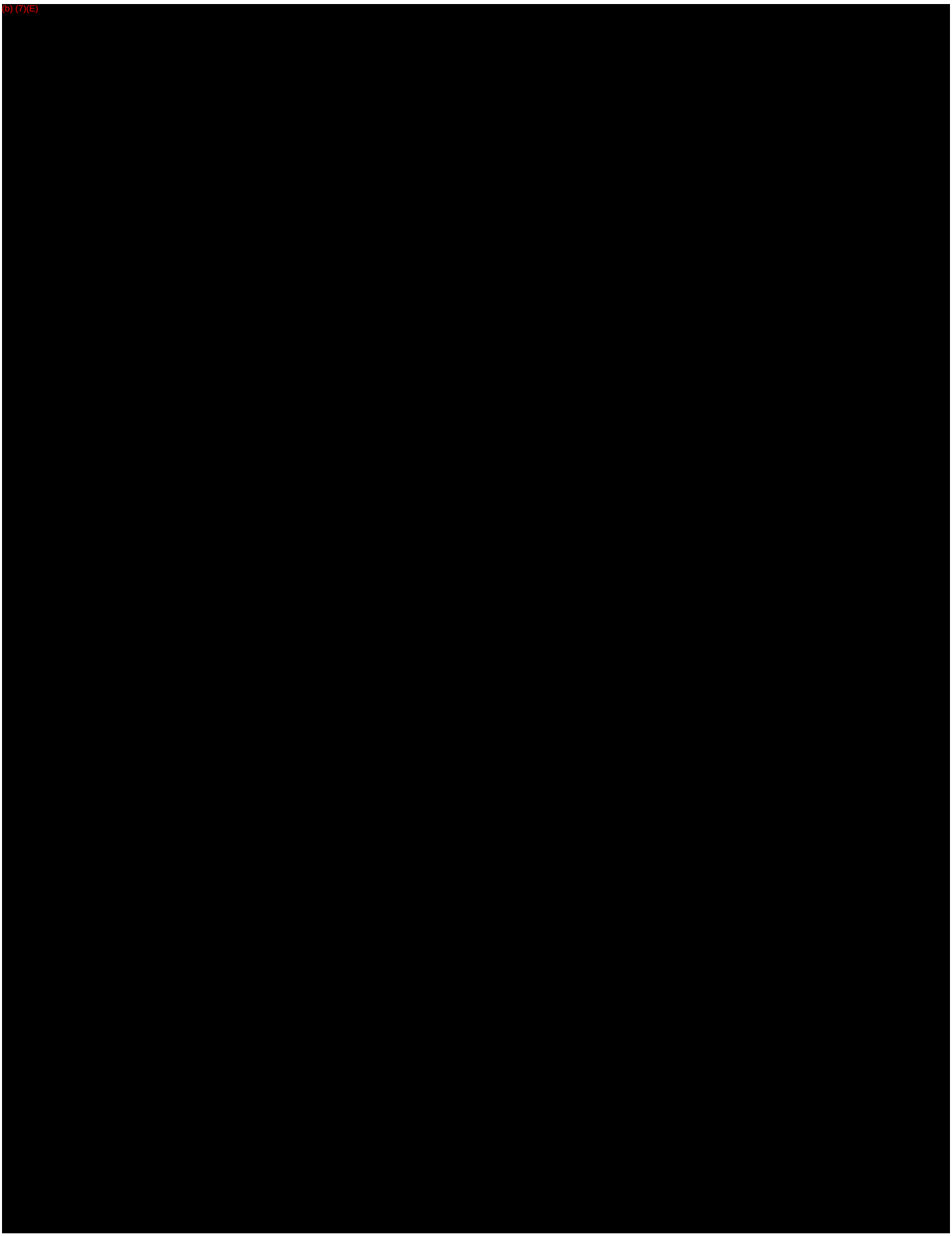

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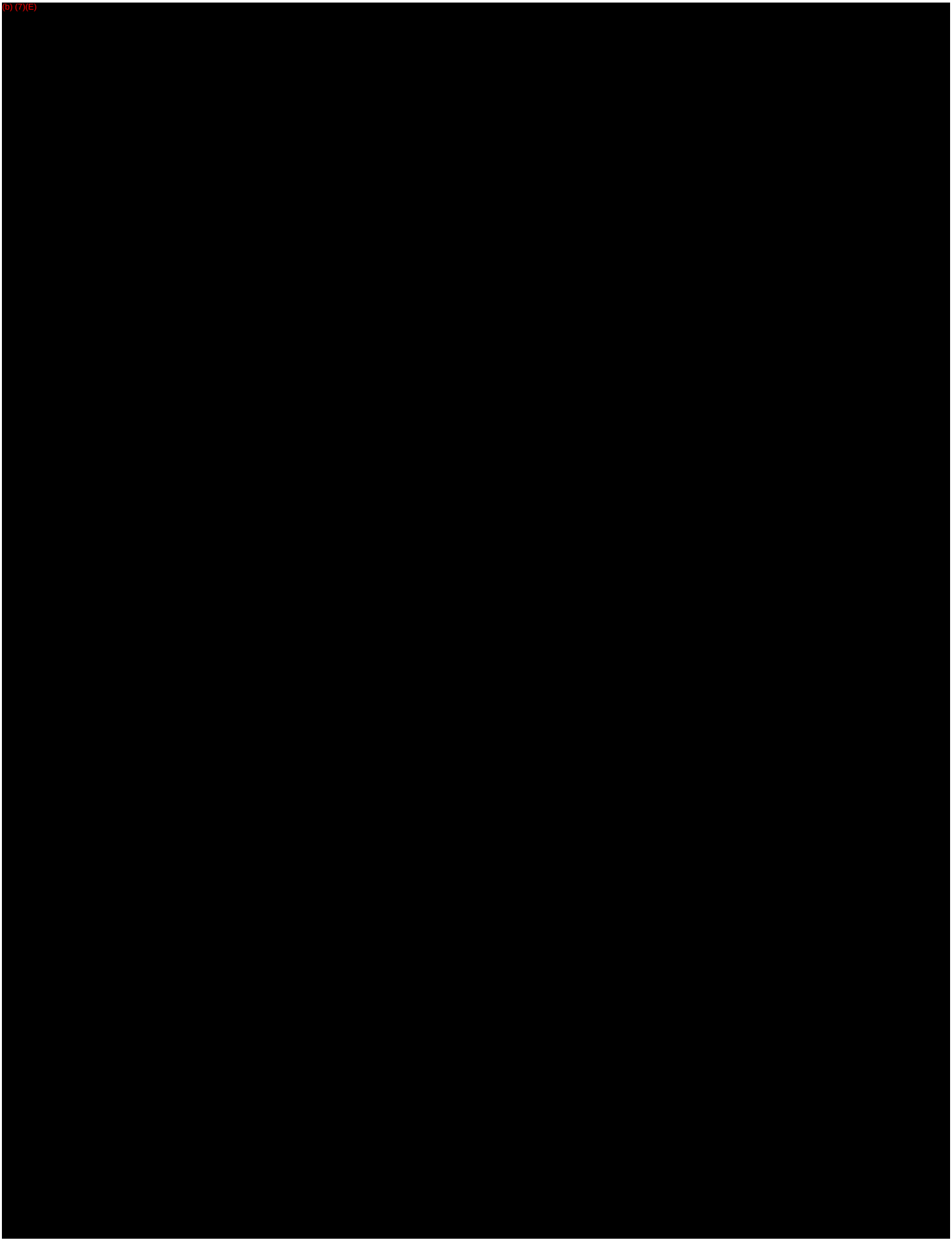
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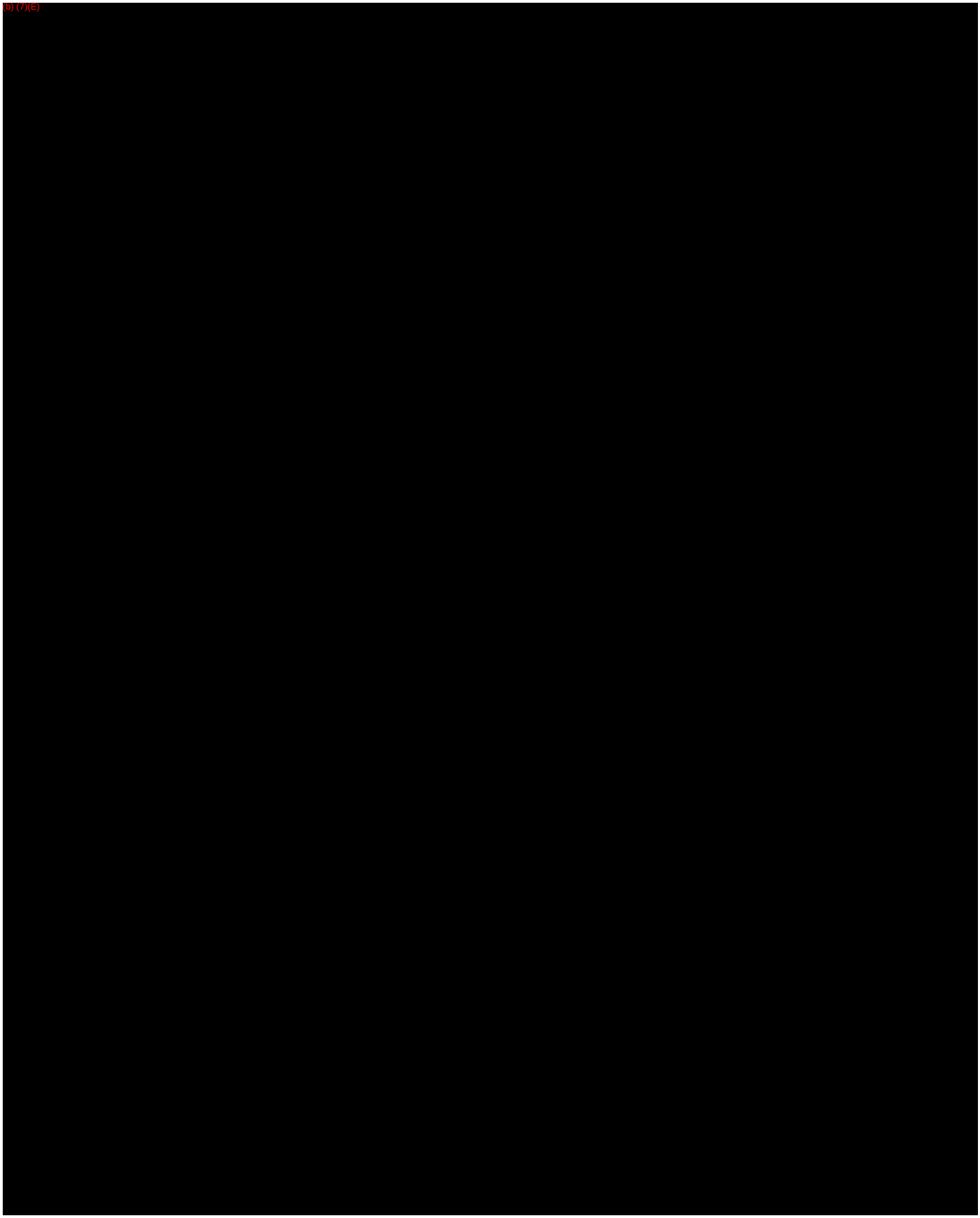

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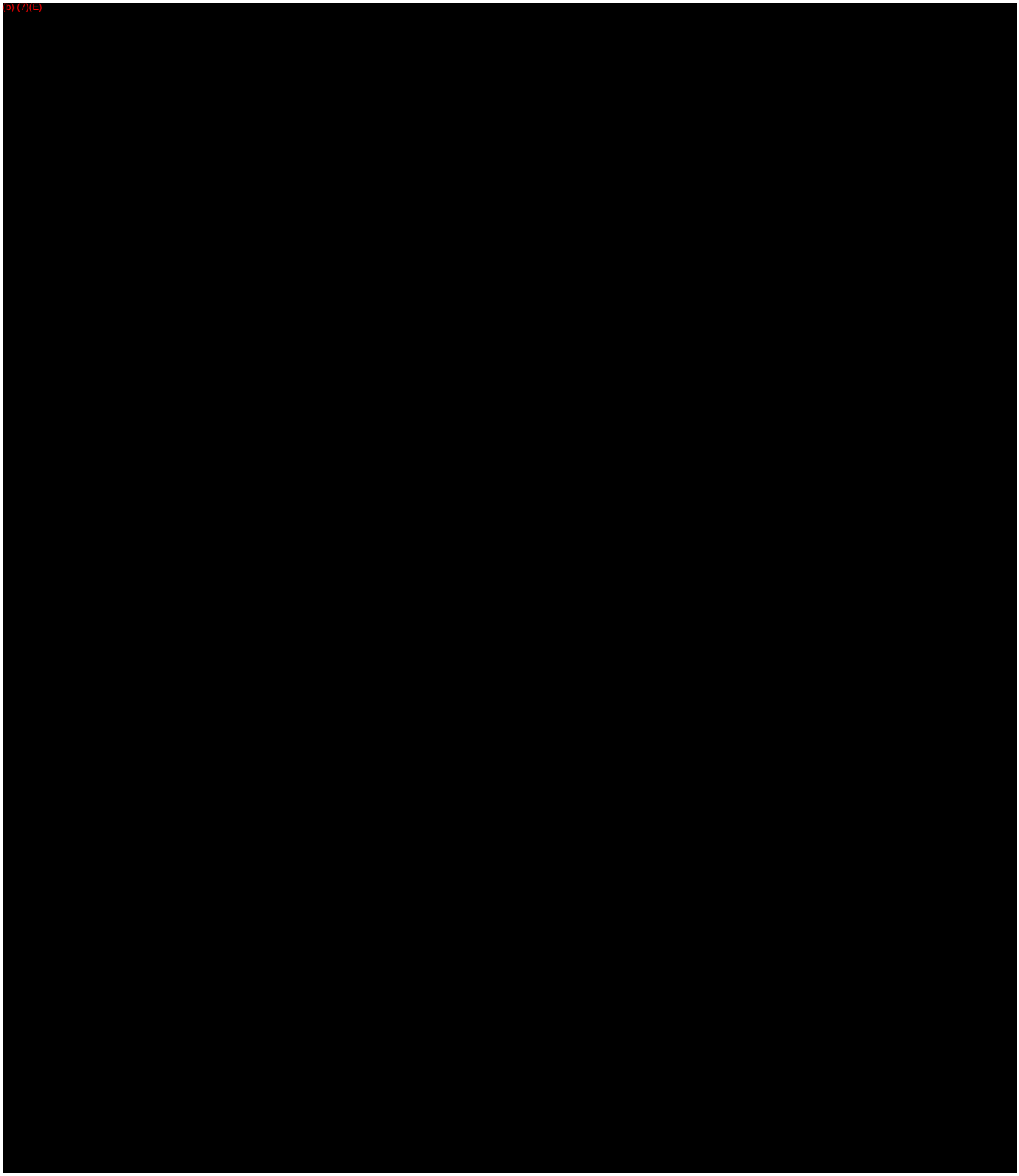

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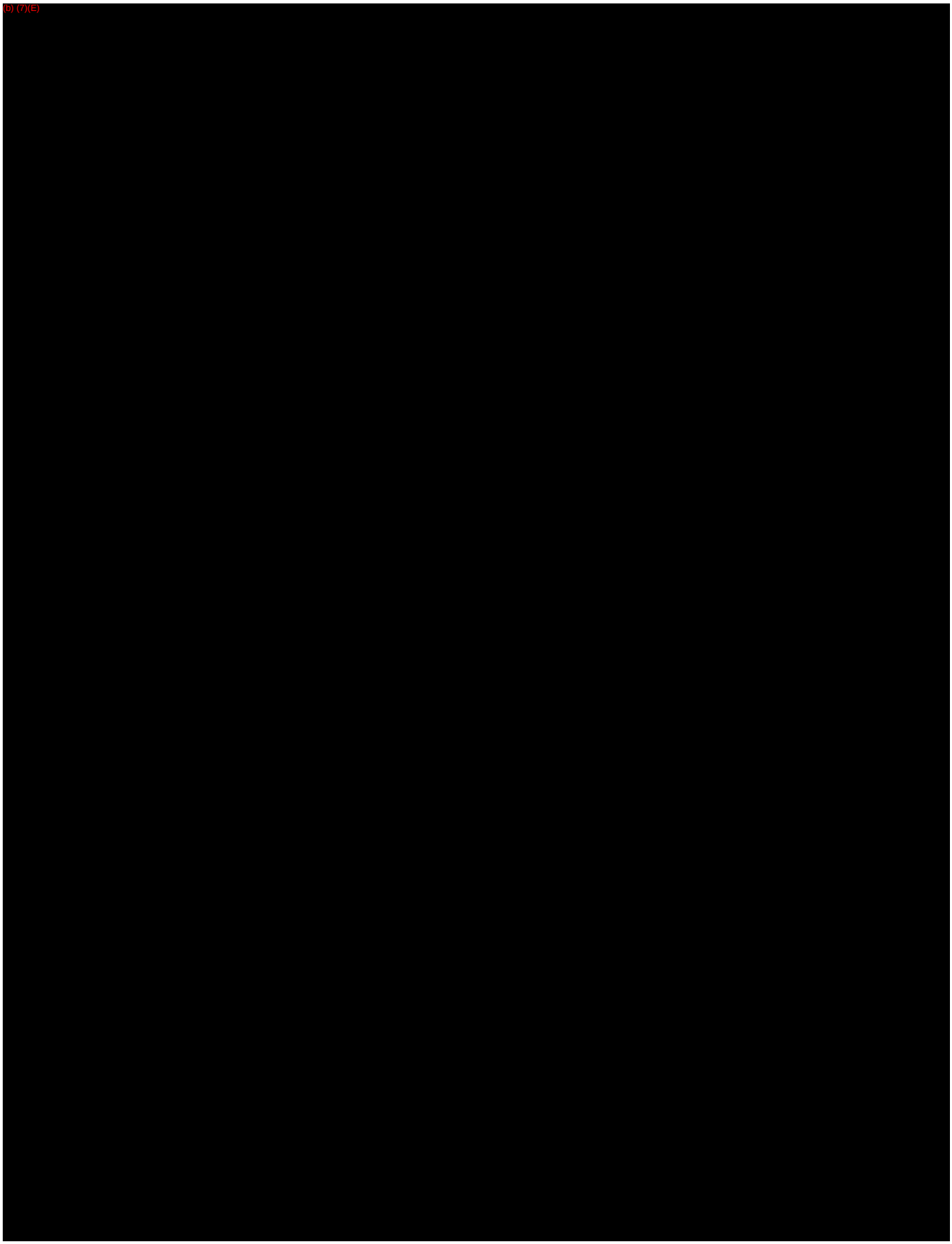

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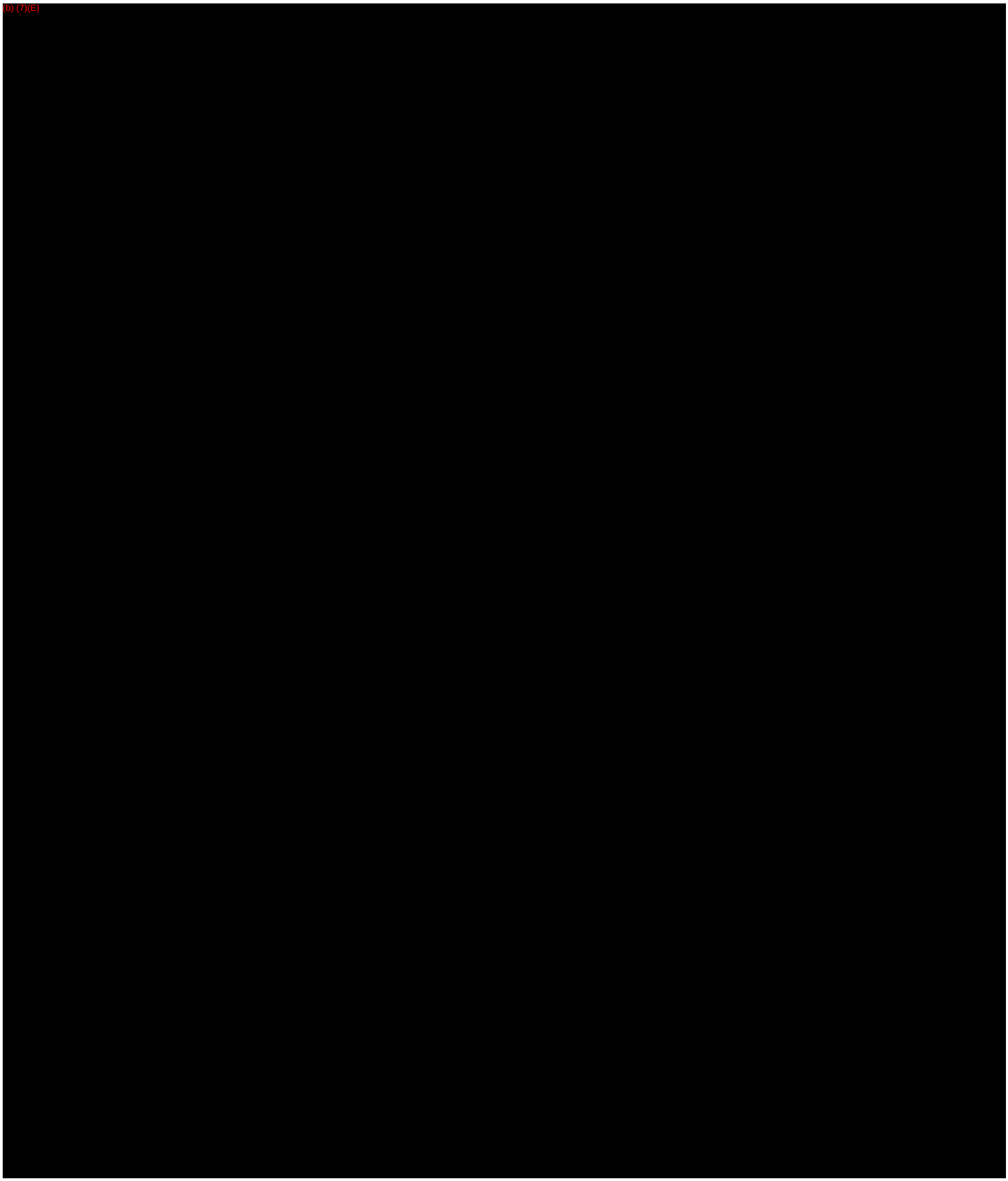

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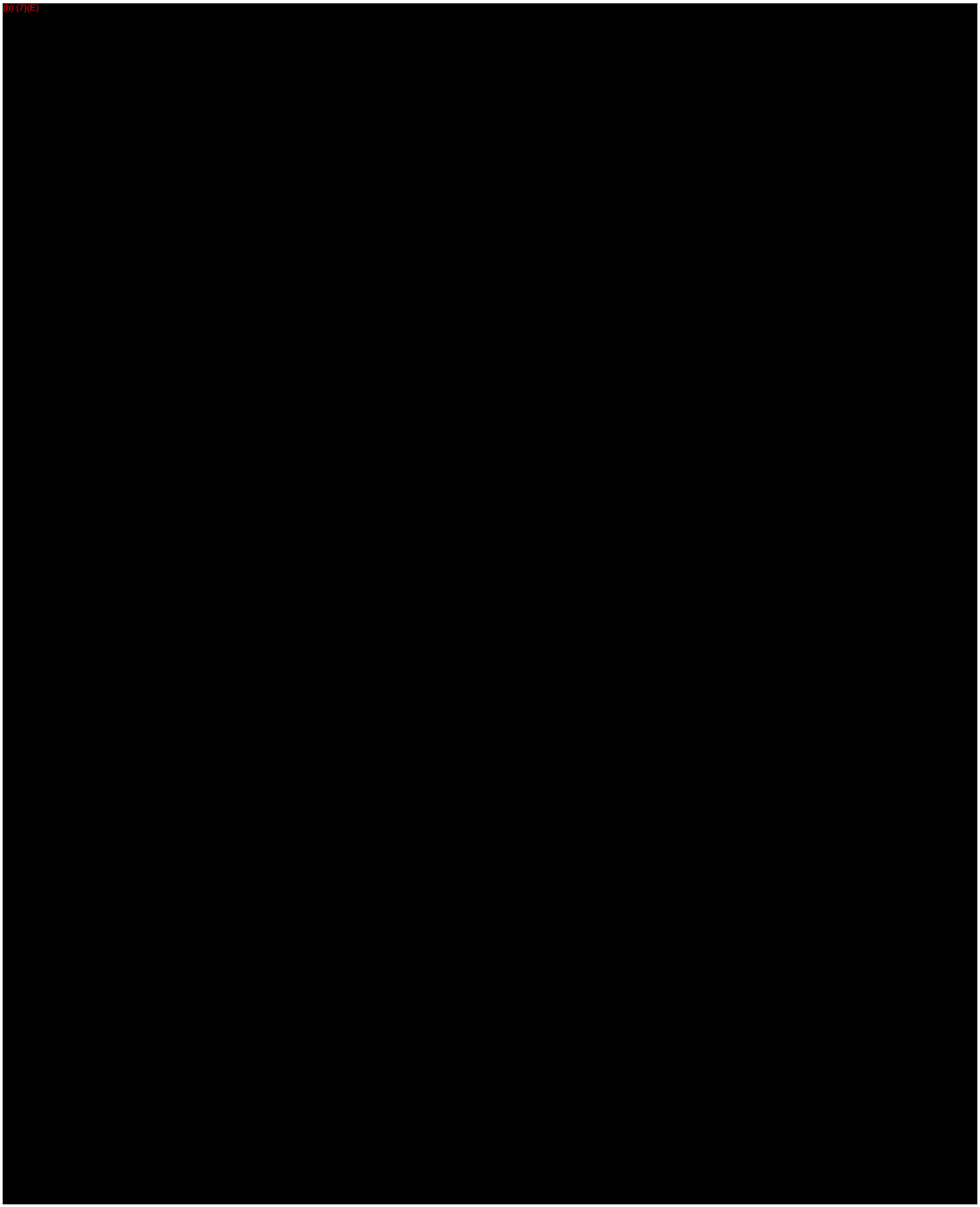


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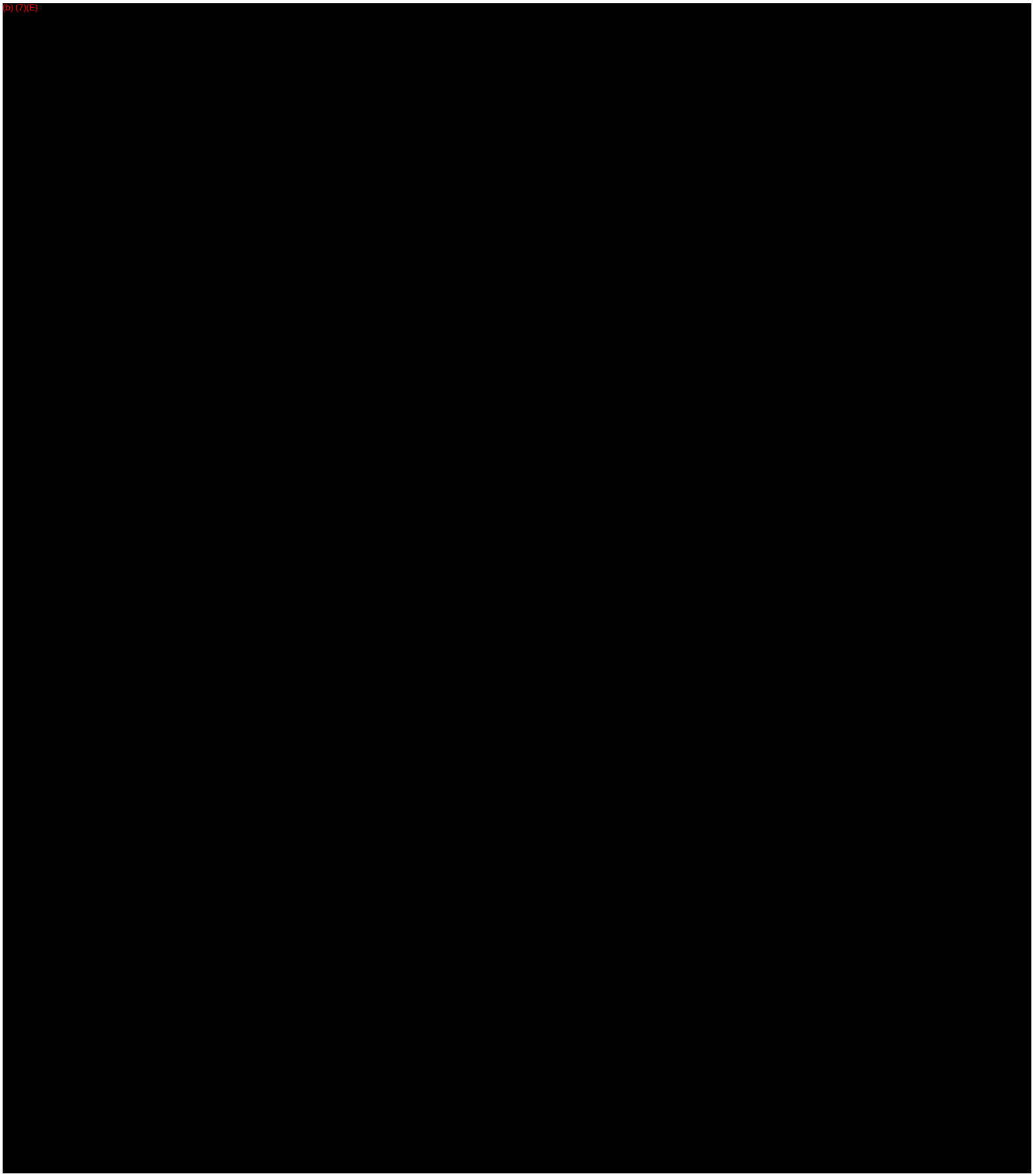


References

Tietz, NW. *Fundamentals of Clinical Chemistry.* Philadelphia, PA. WB Saunders Co; 1976: 994-958.

US Department of Transportation. *Drug Testing Procedures Handbook.* Superintendent of Documents. Washington, DC. Government Printing Office. 20402-9352:22.

Lafolie P, Beck O, Blennow G et al. Importance of Creatinine Analysis of Urine When Screening Abused Drugs. *Clinical Chemistry.* 1991; 37-1927-31.

Goldberger BA, Lewenthal B, Darwin WD, Cone EJ. Intrasubject Variation of Creatinine and Specific Gravity Measurements in Consecution Urine Specimens of Heroin Users. *Clinical Chemistry.* 1995; 41:116-117.

Friedman RB, Young DS. *Effects of Disease on Clinical Laboratory Tests.* 3rd ed. Washington, DC. AACC Press; 1997; 3:147-150.

Needleman SB, Porvaznik M, Ander D. Creatinine Analysis in Since Collection Urine Specimens. *Journal of Forensic Sci.* 1992; 37:1125-1133.

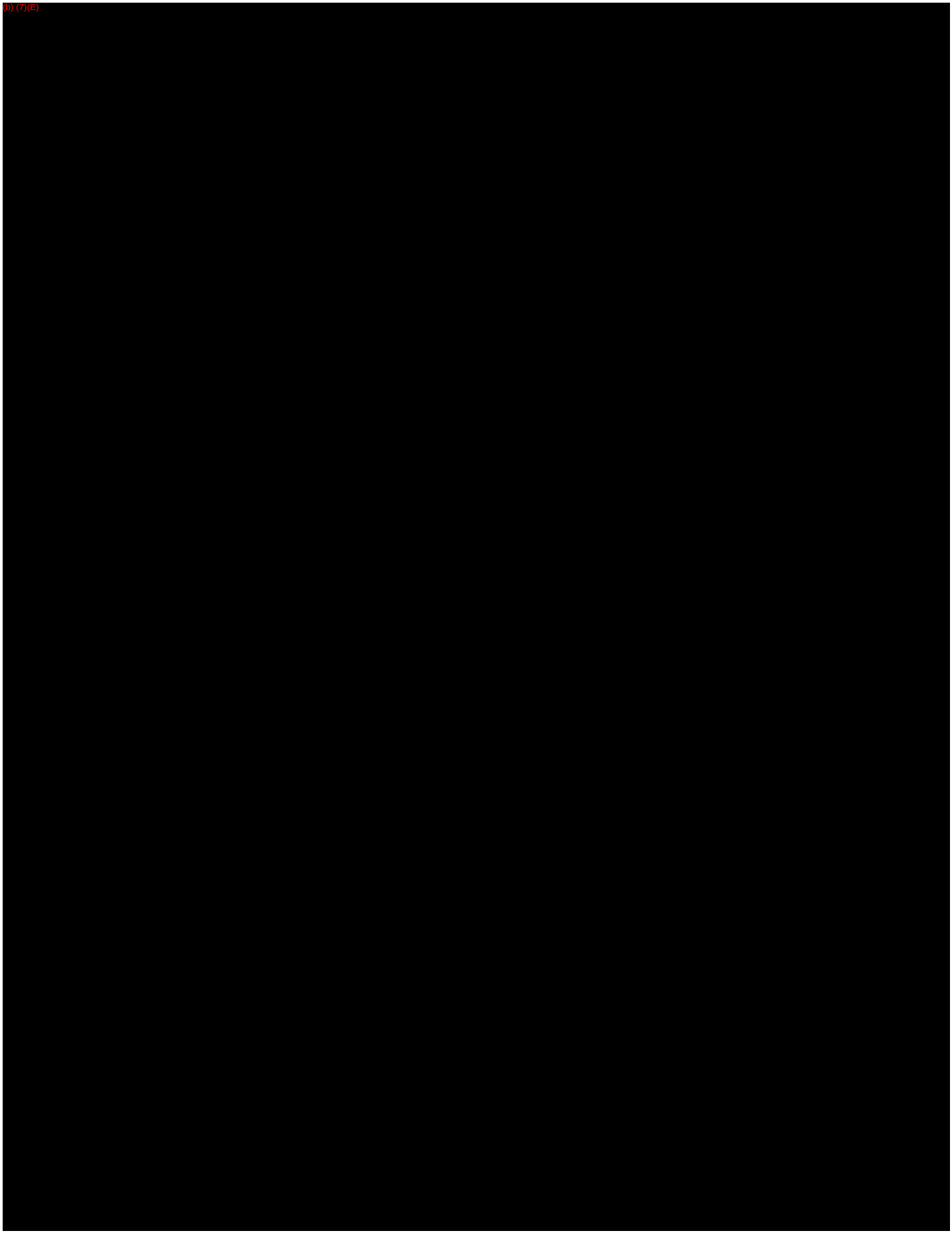
Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), "Mandatory Guidelines for Federal Workplace Drug Testing Programs", Federal Register, April 13, 2004, Volume 69, Number 71 p 19644-19673.

European Laboratory Guidelines for Legally Defensible Workplace Drug Testing, European Workplace Drug Testing Society, Version 1.0.

United Kingdom Laboratory Guidelines for Legally Defensible Drug Testing, Version 1.0, March 2001.

Siemens® Creatinine Validity Test package insert. Siemens Healthcare Diagnostics, Inc. Newark, DE. 2008-03. 3T252UL.7DS_B.

(b) (7)(E)



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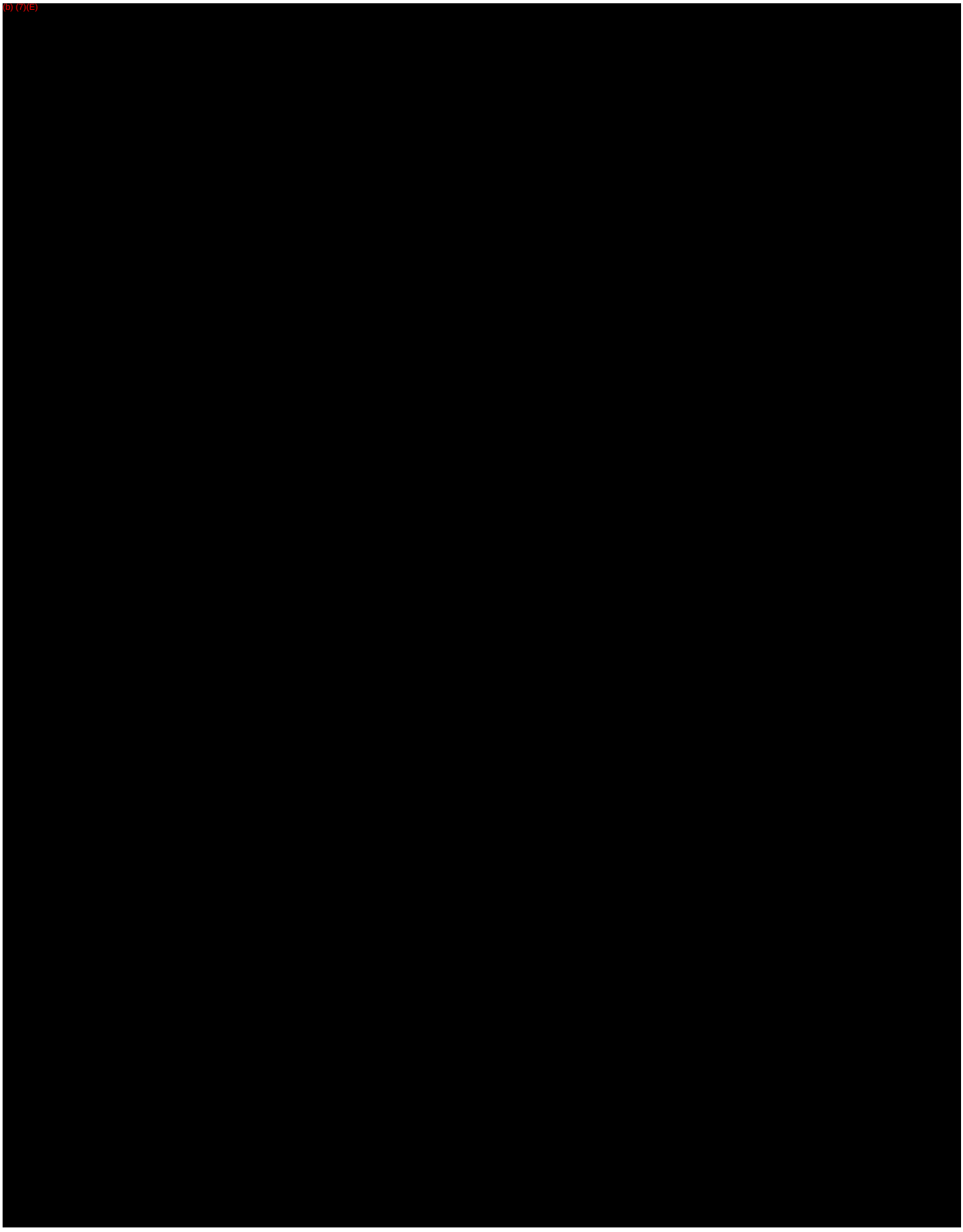

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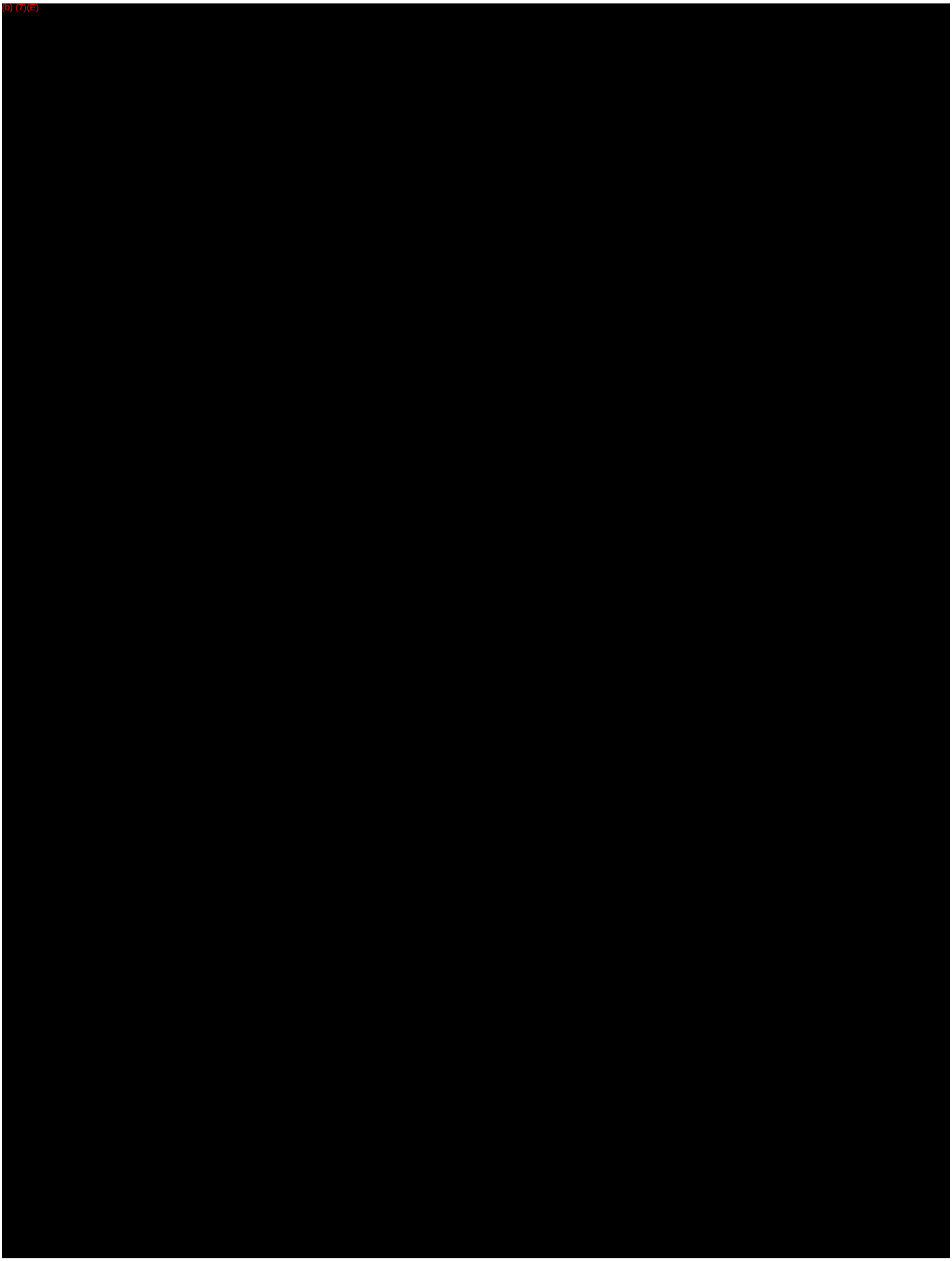


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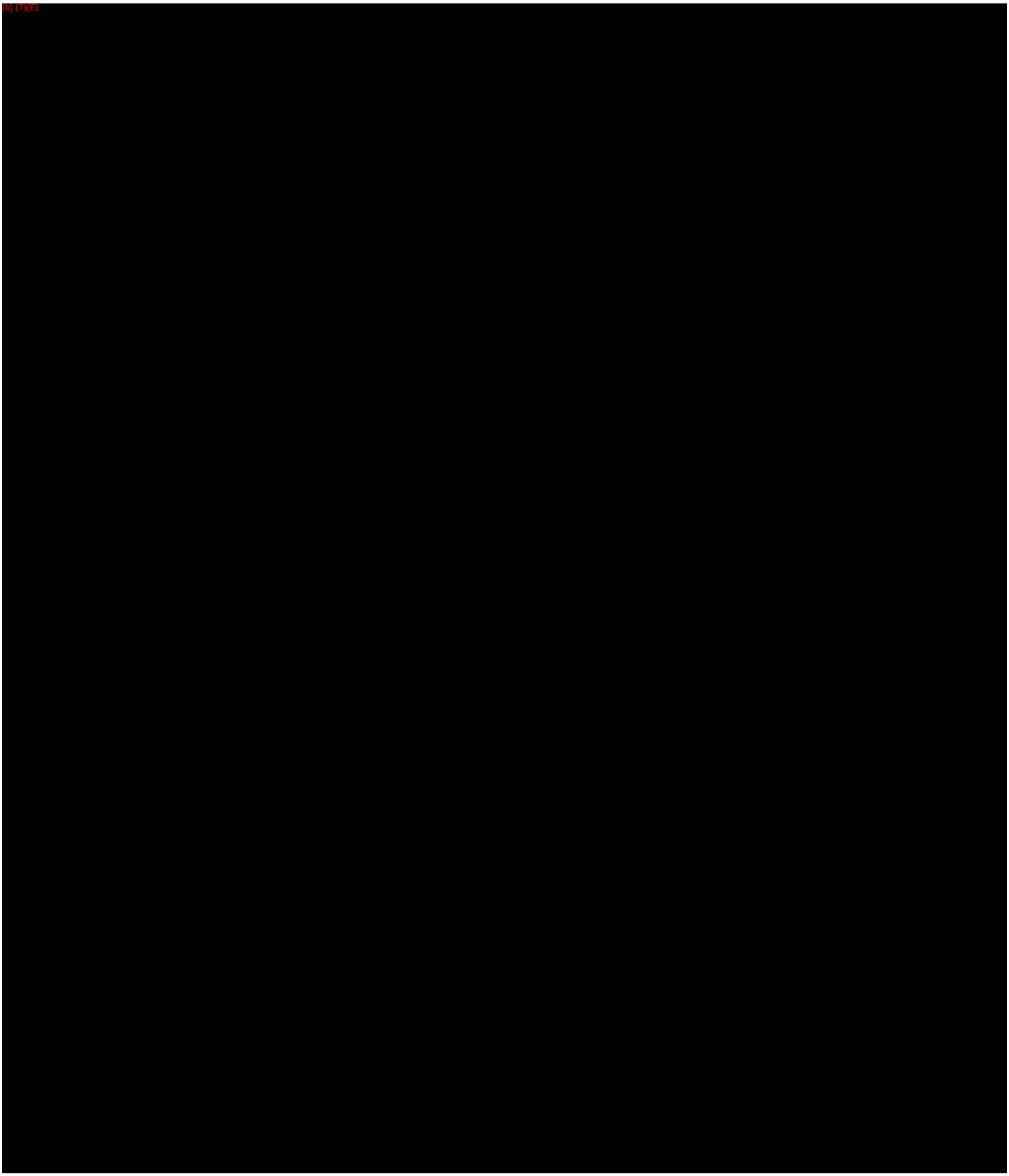

References

Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), "Mandatory Guidelines for Federal Workplace Drug Testing Programs", Federal Register, April 13, 2004, Volume 69, Number 71 p 19644-19673.

Hawks RL, Chiang CN, eds. *Urine Testing for Drugs of Abuse*. NIDA research monograph 73, National Institute on Drug Abuse (NIDA), Rockville, MD: 1986.

Jenkins AJ, Cone EJ. *Pharmacokinetics: Drug Absorption, Distribution, and Elimination.* In: Karch Drug Abuse Handbook. CRC Press, 1998: 151-201.

AHFS Drug Information '87, American Society of Hospital Pharmacists, Inc, 1987: 1105-1107.

Baselt RC, Cravey RH. *Disposition of Toxic Drugs and Chemicals in Man* 3rd ed. Chemical Toxicology Institute. 2000.

Oellerich M. Enzyme immunoassays in clinical chemistry: Present status and trends. *J Clin Chem Clin Biochem*. 1980;18:197–208.

Handbook of Non-prescription Drugs, Washington, DC, American Pharmaceutical Association, 2002:212-216.

Emit® II Plus Amphetamines Assay package insert. Siemens Healthcare Diagnostics, Inc. Newark, DE. 2009-09. 9C122UL.4DS_US_C

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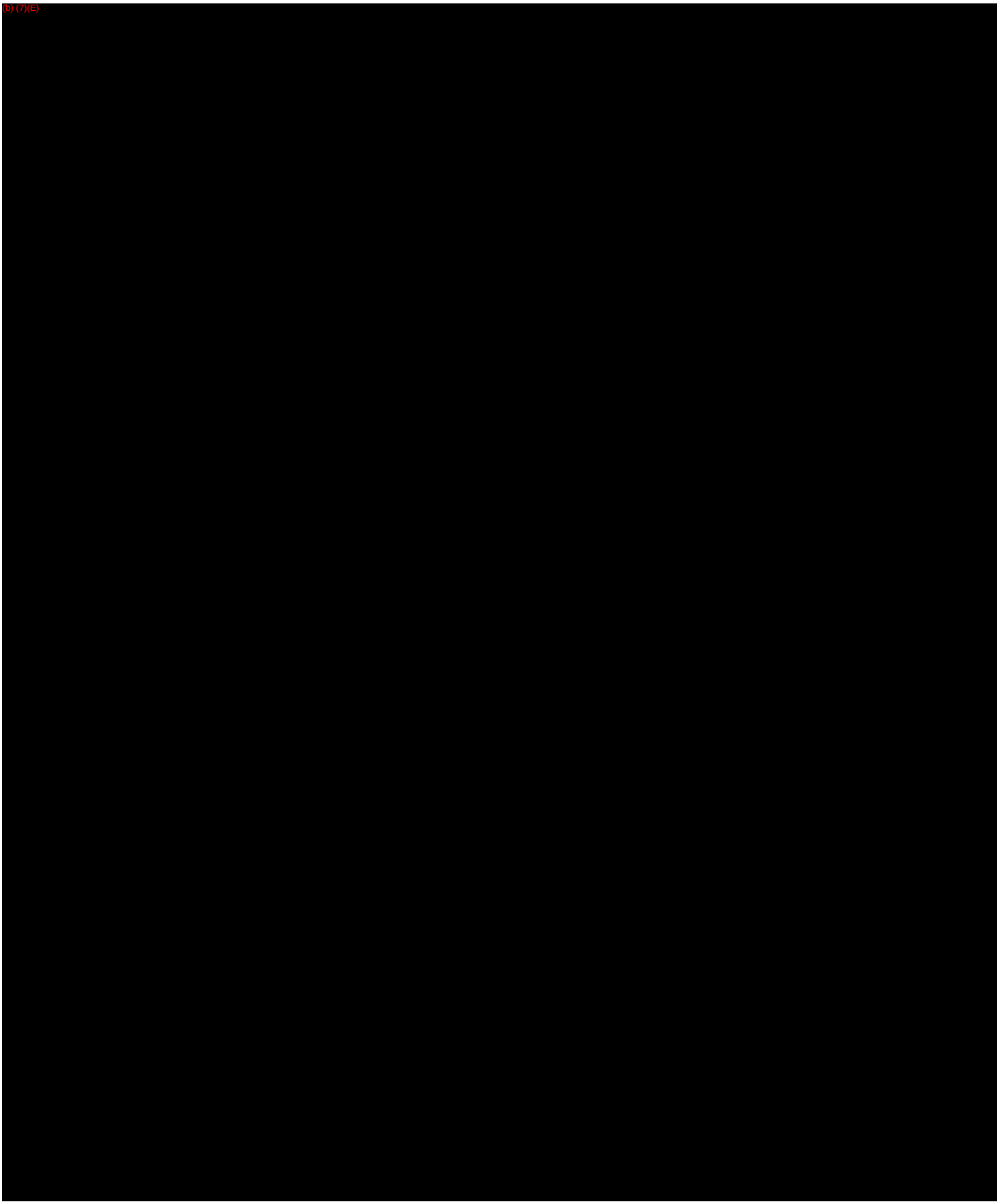

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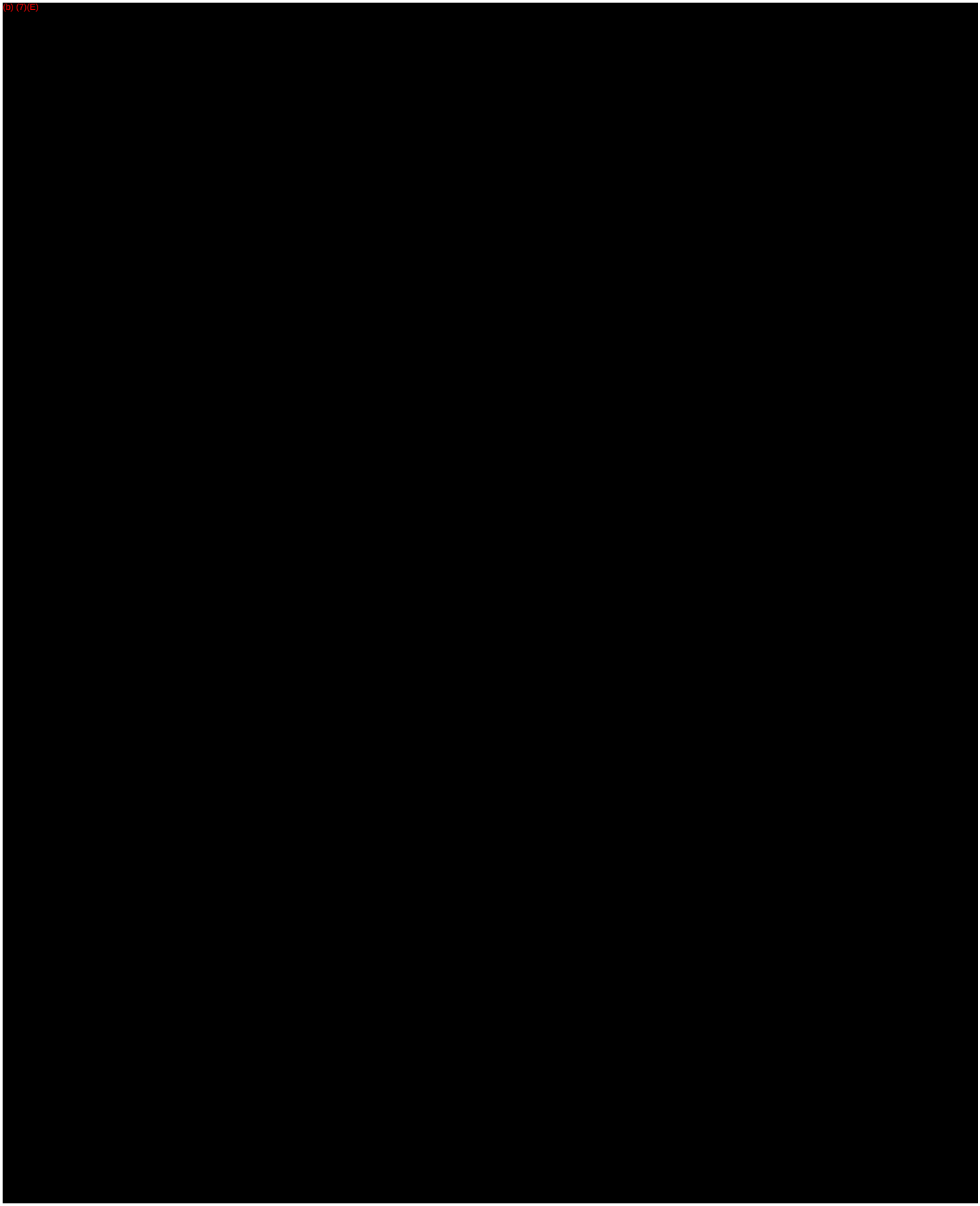

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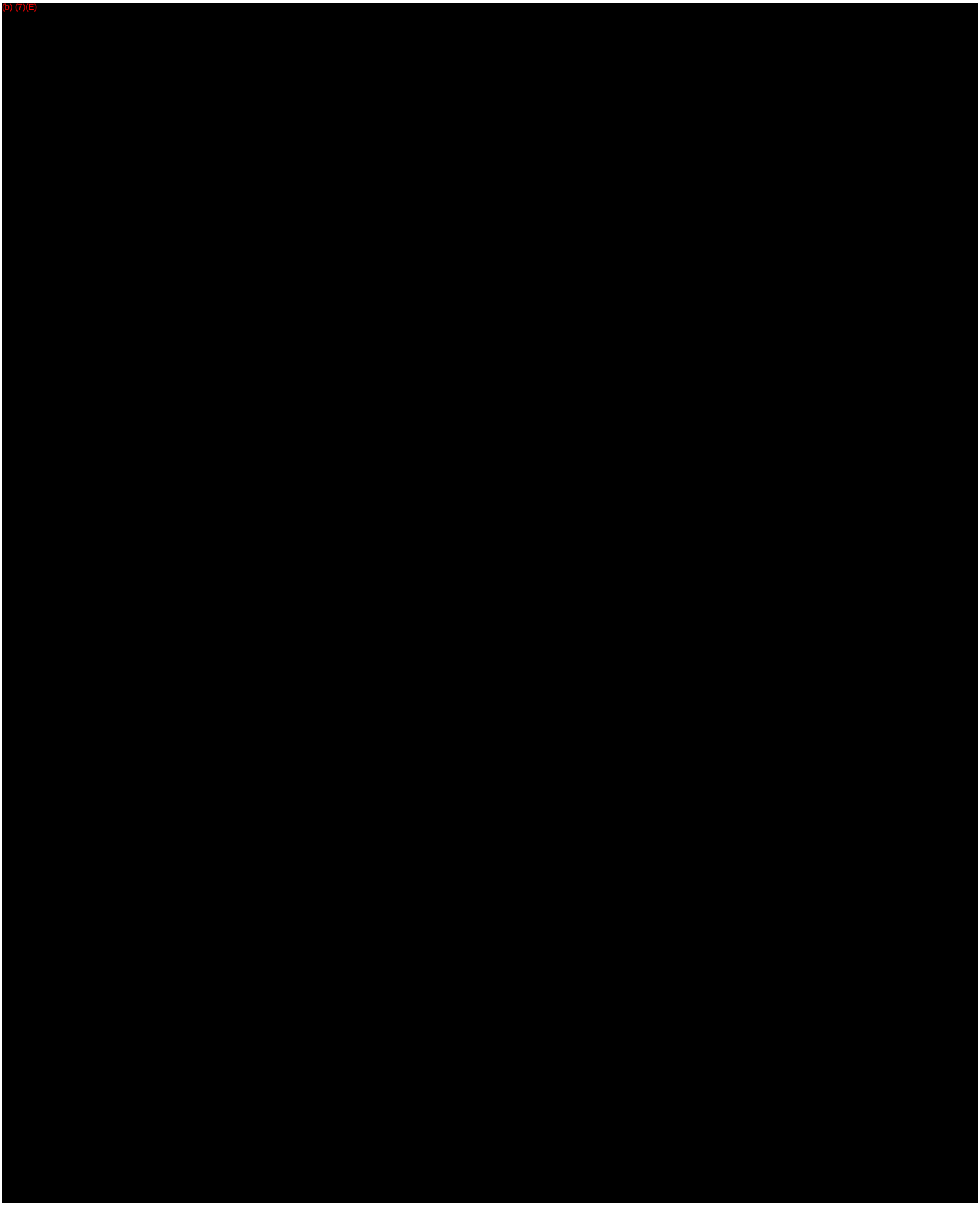

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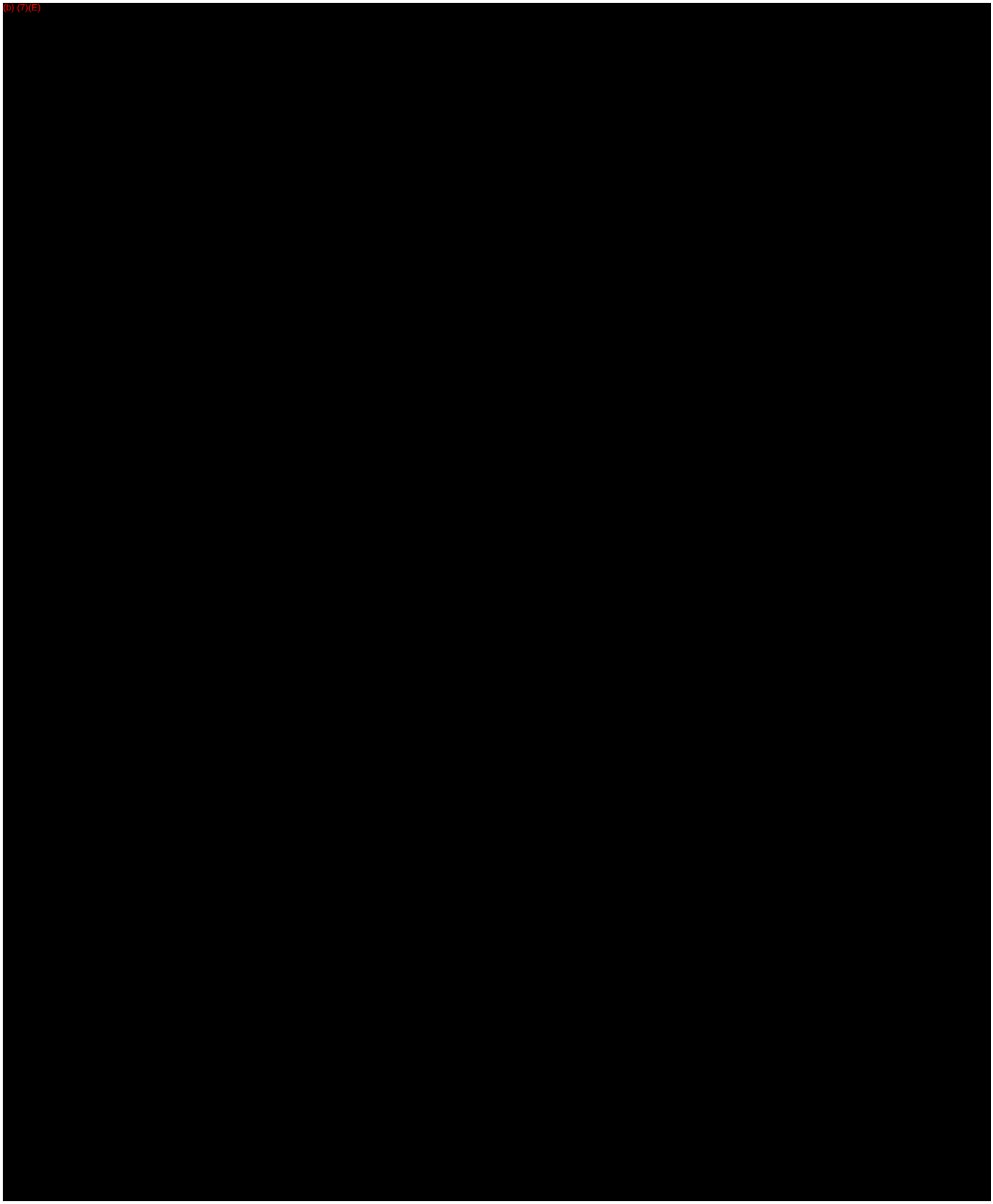

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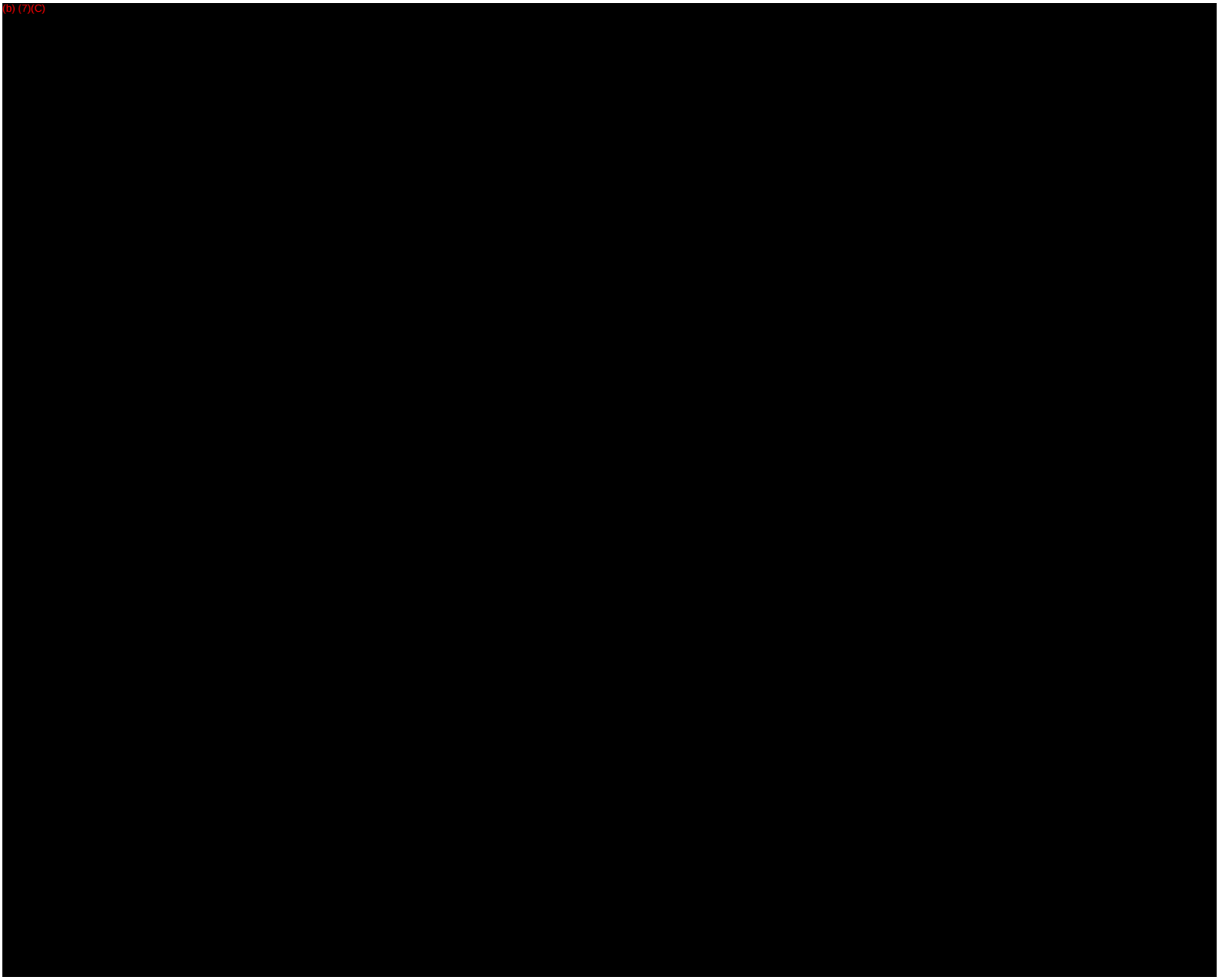

References

Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), "Mandatory Guidelines for Federal Workplace Drug Testing Programs", Federal Register, April 13, 2004, Volume 69, Number 71 p 19644-19673.

Hawks RL, Chiang CN, eds. *Urine Testing for Drugs of Abuse*. NIDA research monograph 73, National Institute on Drug Abuse (NIDA), Rockville, MD: 1986.

Wyngaarden JB, Smith LH Jr, eds. *Cecil Textbook of Medicine*. Philadelphia, PA: WB Saunders Co. 1988:54-5.

Pearman K. Cocaine: A review. *J Laryngol Otol*. 1979; 93:1191-9.

Stewart DJ et al. Cocaine metabolism: Cocaine and norcocaine hydrolysis by liver and serum

esterases. *Clin Pharmacol Ther*. 1978;25:464–8.

Hamilton HE et al. Cocaine and benzoylecgonine excretion in humans. *J Forensic Sci Sas*. 1977;22:697–70.

Van Dyke C et al. Urinary excretion of immunologically reactive metabolite(s) after intranasal administration of cocaine as followed by enzyme immunoassay. *Clin Chem*. 1977;23:241–4.

Ellenhorn MJ, Barceloux DG. *Medical Toxicology*. New York, NY: Elsevier Science Publishing Company, Inc. 1988:644–59.

Logan MJ et al. Quantitative determination of benzoylecgonine and cocaine in human biofluids by gas-liquid chromatography. *Anal Chem*. 1977;49:1965–69.

Lindgren JE. Guide to the analysis of cocaine and its metabolites in biological material. *J Ethnopharmacol*. 1981;3:337–51.

Oellerich M. Enzyme immunoassays in clinical chemistry: present status and trends. *J Clin Chem Clin Biochem*. 1980;18:197–208.

Emit® II Plus Cocaine Metabolite Assay package insert. Siemens Healthcare Diagnostics, Inc. Newark, DE. 2008-03. 9H522UL.4DS_US_B.

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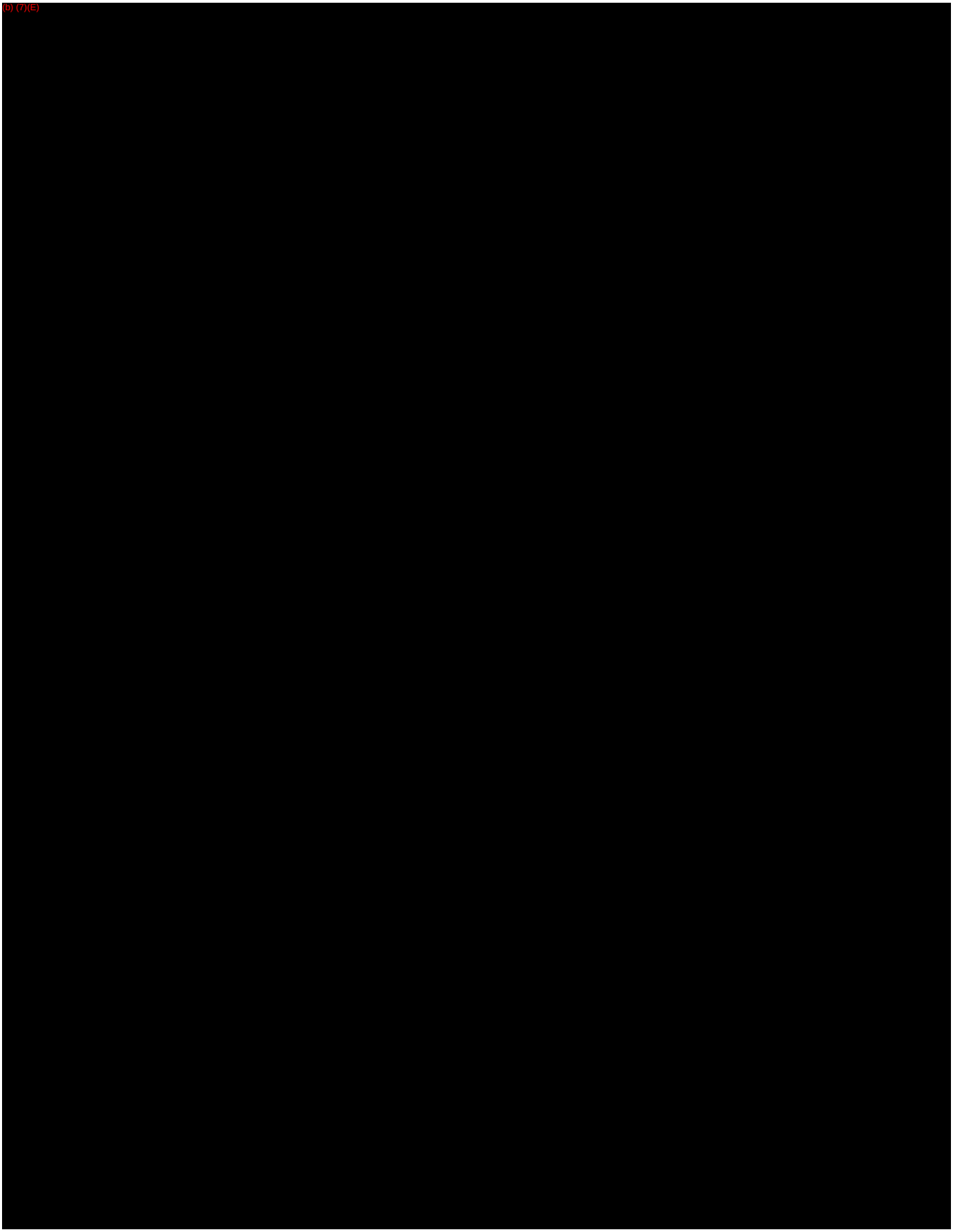

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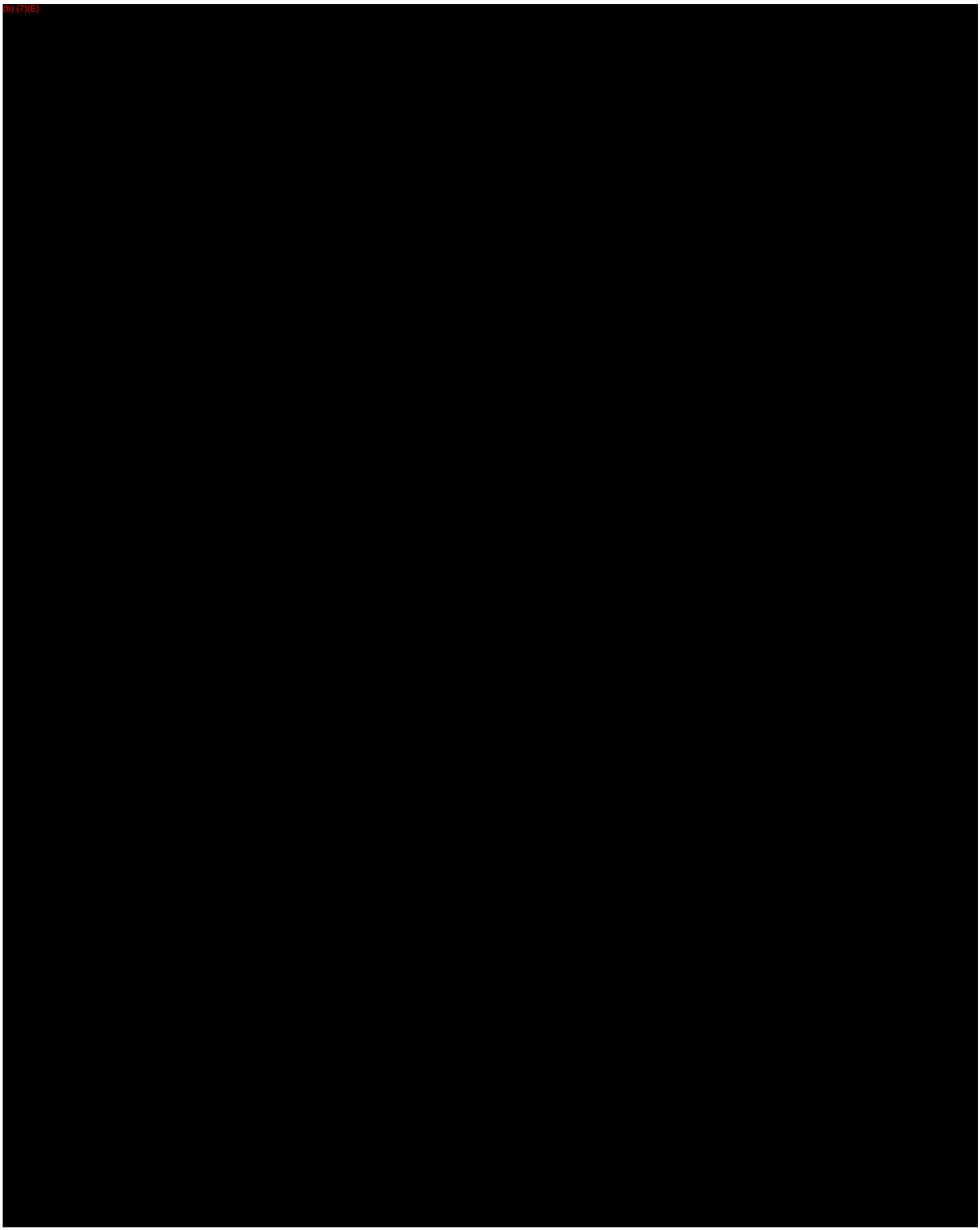


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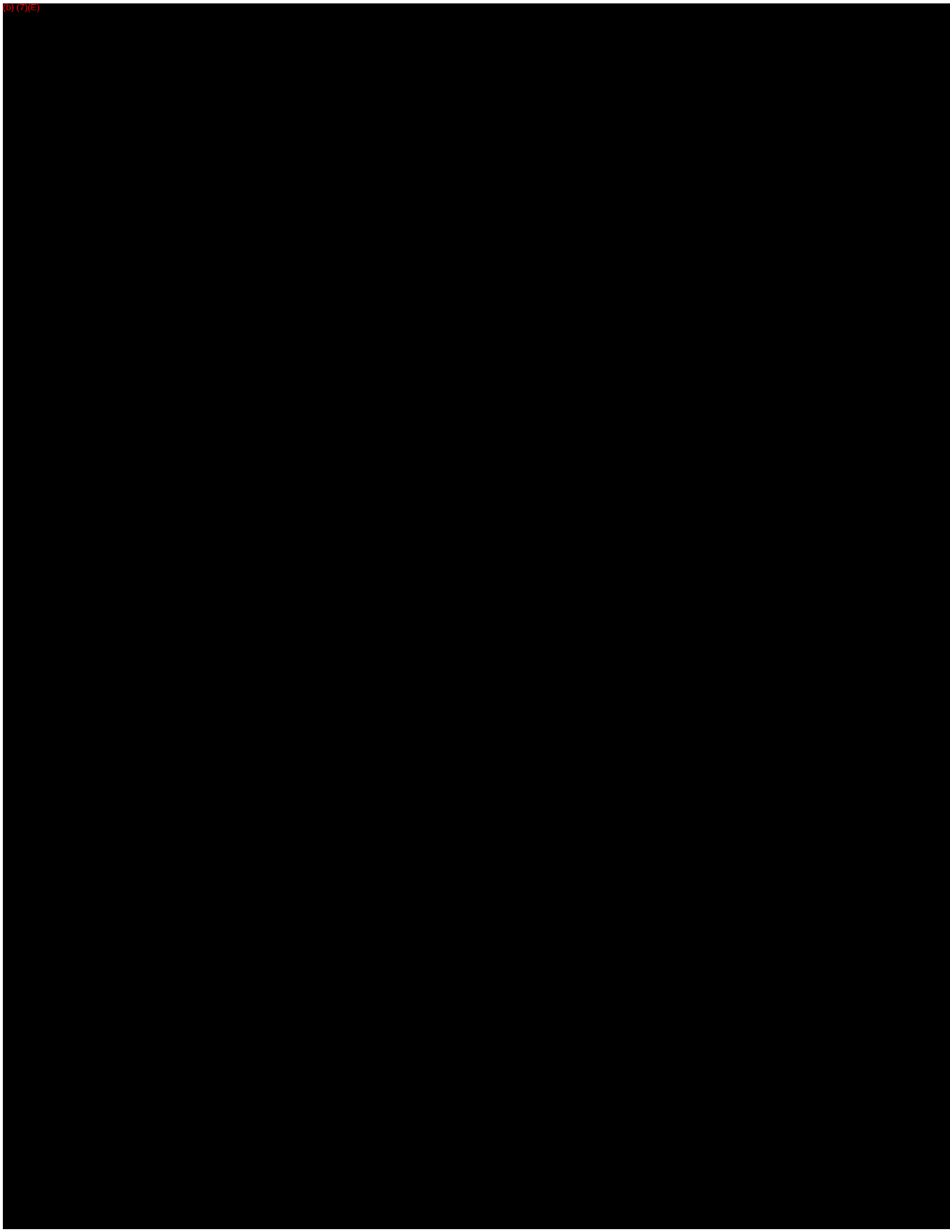

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References

Hawks RL, Chiang CN, eds. *Urine Testing for Drugs of Abuse*. NIDA research monograph 73, National Institute on Drug Abuse (NIDA), Rockville, MD: 1986.

Wyngarrden JB, Smith LH Jr eds. *Cecil Textbook of Medicine.* Philadelphia , PA. WB Saunders Co. 1988:57-60.

Ellenhorn MJ, Barceloux DG. *Medical Toxicology*. New York, NY. Elsevier Science Publishing Company, Inc. 1988:714-718.

Woolf DS: Opioids, In: Bennett N, Vourakis C, and Woolf DS eds: *Substance Abuse: Pharmacologic, Developmental, and Clinical Perspectives*. New York, NY: John Wiley and Sons, 1983:70-85.

Hofmann FE. *A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects*. New York, NY: Oxford University Press. 1983.

Baselt RC, Cravey RH. *Disposition of Toxic Drugs and Chemicals in Man*, 3rd ed. Chicago, IL: ear Book Medical Publishers, Inc; 1989: 379-383

Gorodetzky CW. Detection of drugs of abuse in biological fluids. In: Martin WR, ed. *Drug Addiction I*. New York, NY. Springer-Verlag. 1977:319–409.

Oellerich M. Enzyme immunoassays in clinical chemistry: Present status and trends. *J Clin Chem Clin Biochem*. 1980;18:197–208.

Emit® II Plus Methadone Assay package insert. Siemens Healthcare Diagnostics, Inc. Newark, DE. 2008-03. 9E022UL.9DS_US_B.

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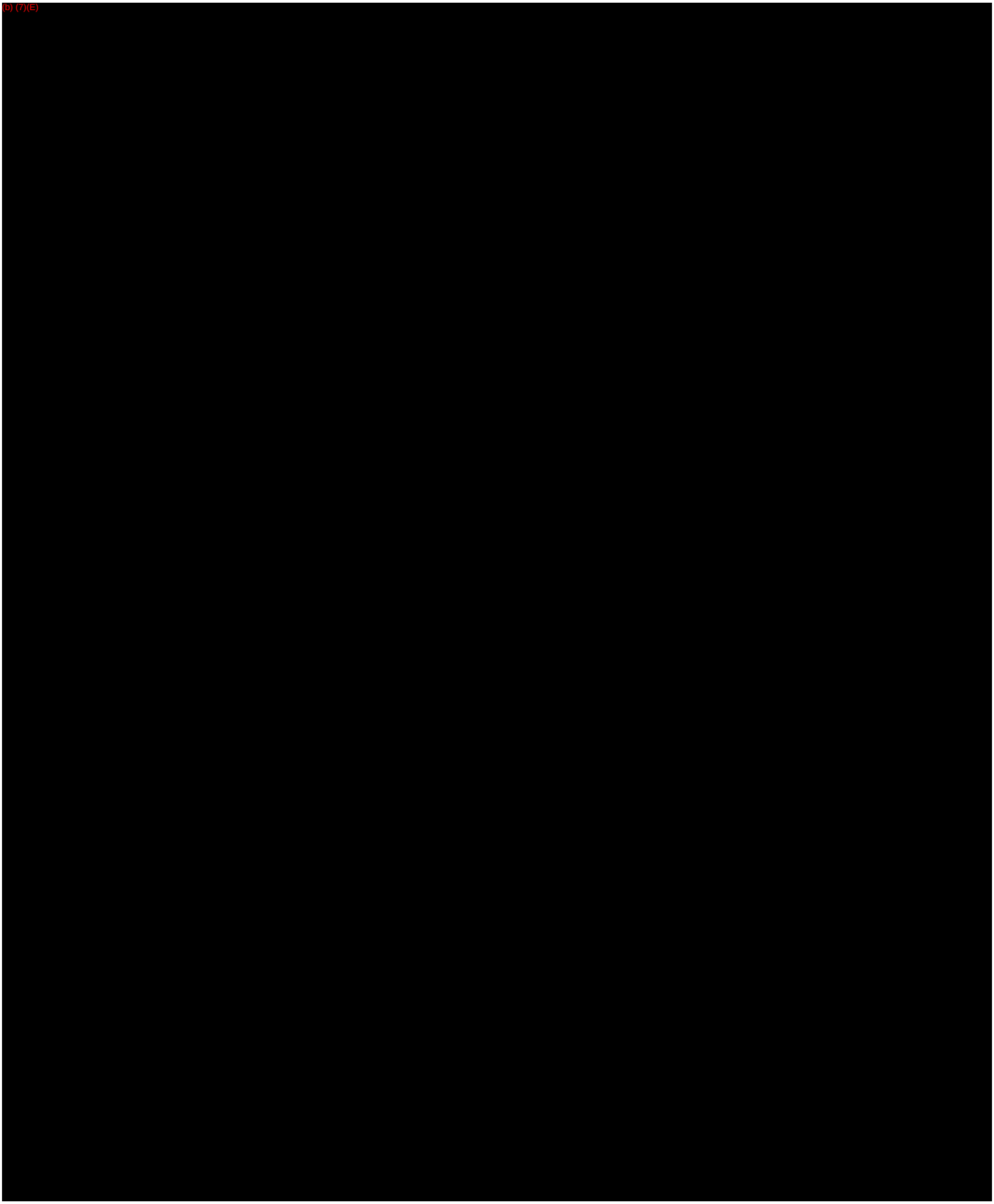

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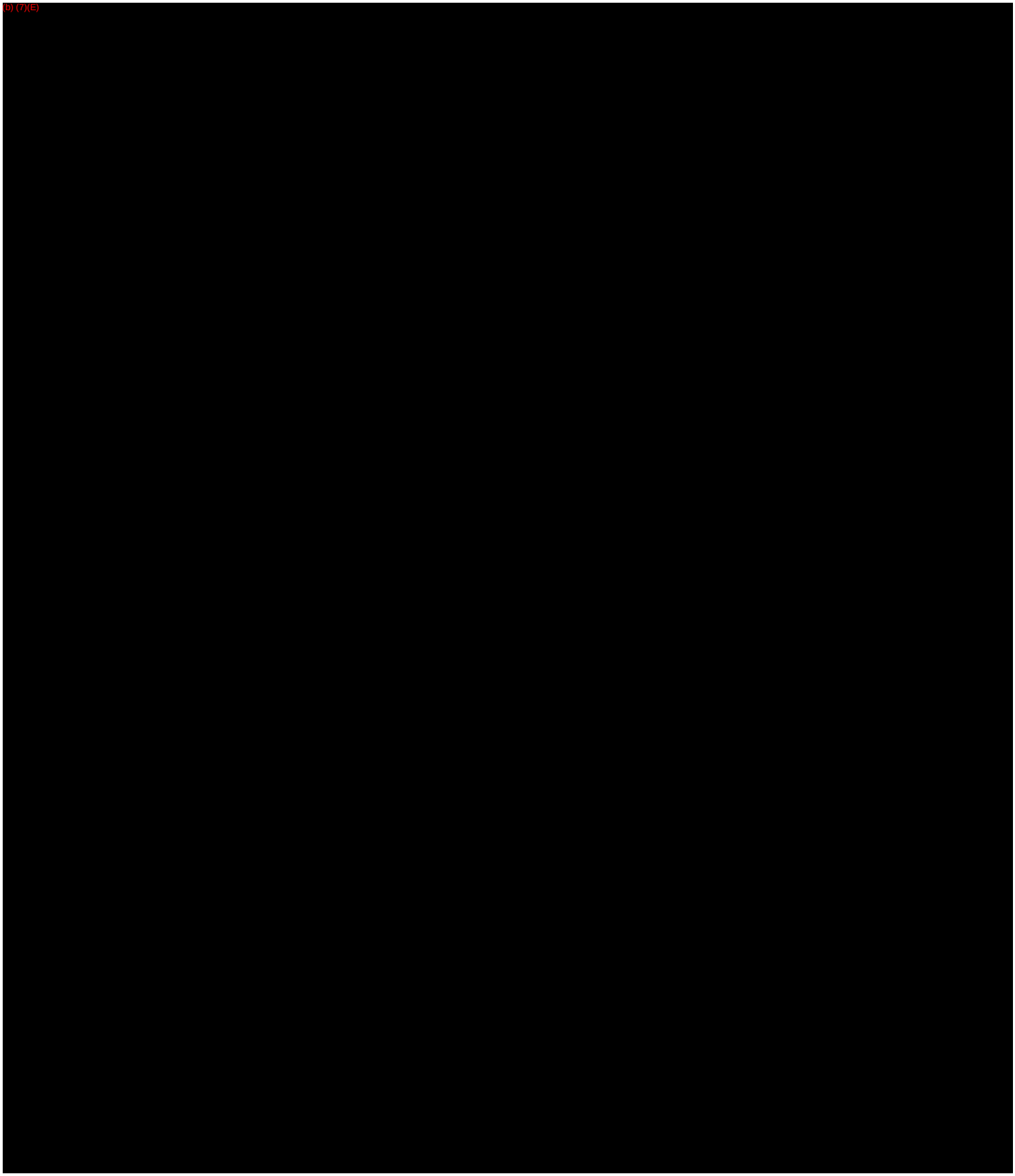

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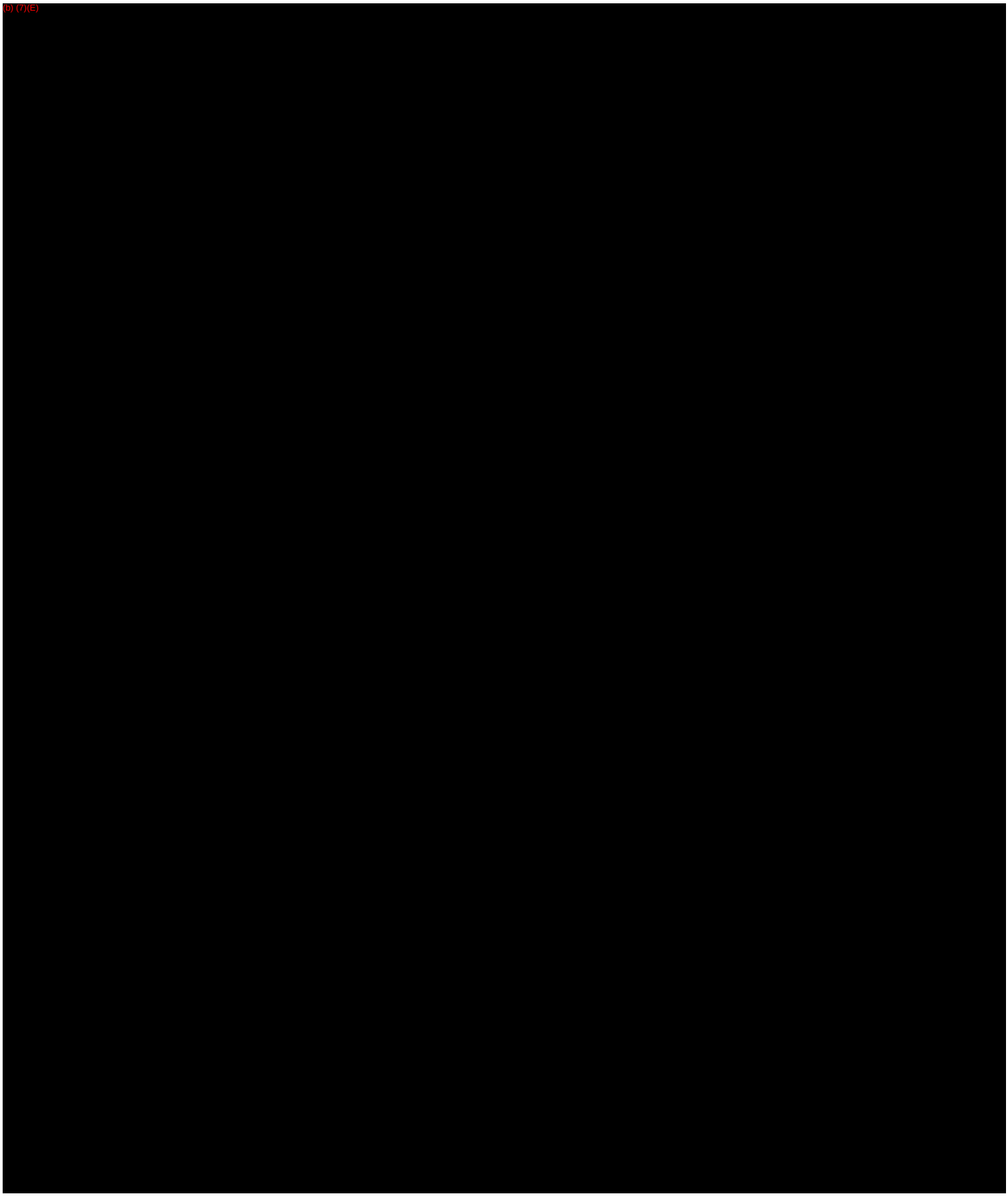


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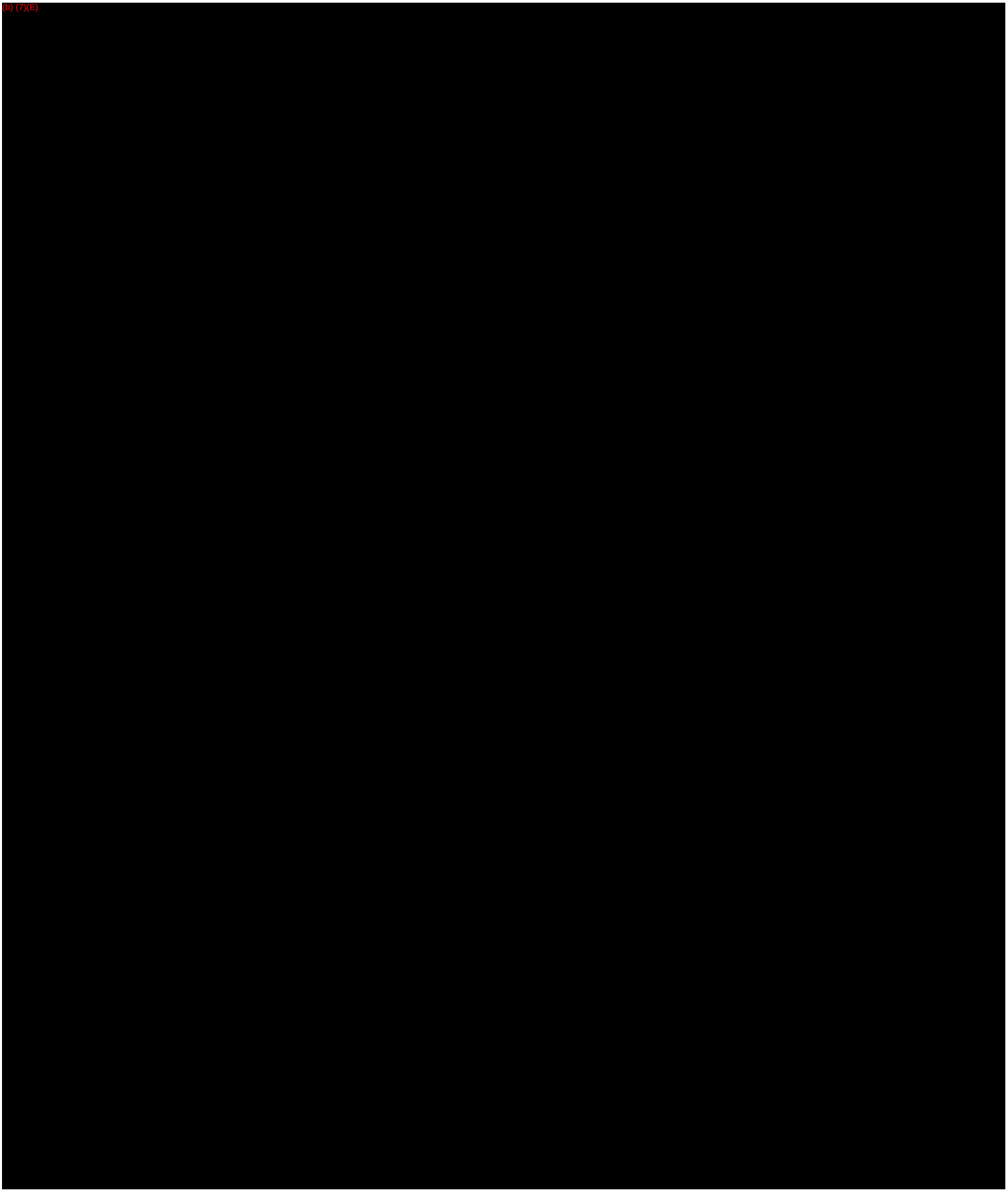

References

Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), "Mandatory Guidelines for Federal Workplace Drug Testing Programs", Federal Register, April 13, 2004, Volume 69, Number 71 p 19644-19673.

Hawks RL, Chiang CN, eds. *Urine Testing for Drugs of Abuse*. NIDA research monograph 73, National Institute on Drug Abuse (NIDA), Rockville, MD: 1986.

Ellenhorn MJ, Barceloux DG. *Medical Toxicology*. New York, NY: Elsevier Science Publishing Company, Inc. 1988, pp 689-717.

Wyngarrden JB. Smith LH Jr (eds). *Cecil Textbook of Medicine*. Philadelphia, PA. WB Saunders Co; 1988, pp 55-57.

Gorodetzky CW. Detection of drugs of abuse in biological fluids. In: Martin WR, ed. *Drug Addiction I*. New York, NY: Springer-Verlag, 1977, pp 319-409.

Oellerich M. Enzyme immunoassays in clinical chemistry: present status and trends. *J Clin Chem Clin Biochem*. 1980; 18:197-208.

Hayes LW, Krasselt WG, Mueggler PA. Concentrations of morphine and codeine in serum and urine after ingestion of poppy seeds. *Clin Chem*,1987, 33(6):806-808

Baselt RC, Cravey RH. Disposition of Toxic Drugs and Chemicals in Man, 3rd ed. Chicago, IL: Year Book Medical Publishers Inc; 1989, p 488.

Emit® II Plus Opiate Assay package insert. Siemens Healthcare Diagnostics, Inc. Newark, DE. 2009-11. 9B322UL.10DS_US_C

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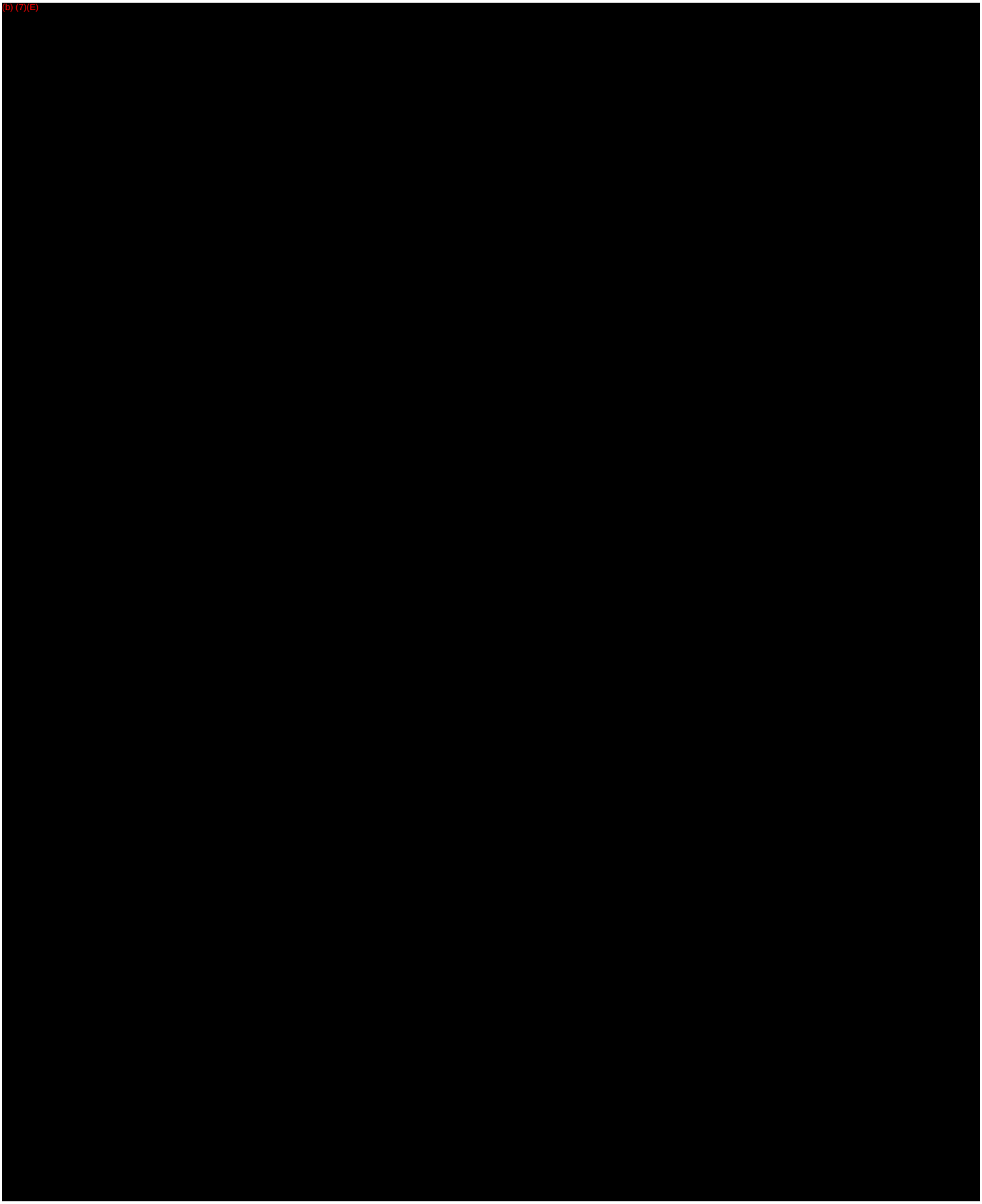

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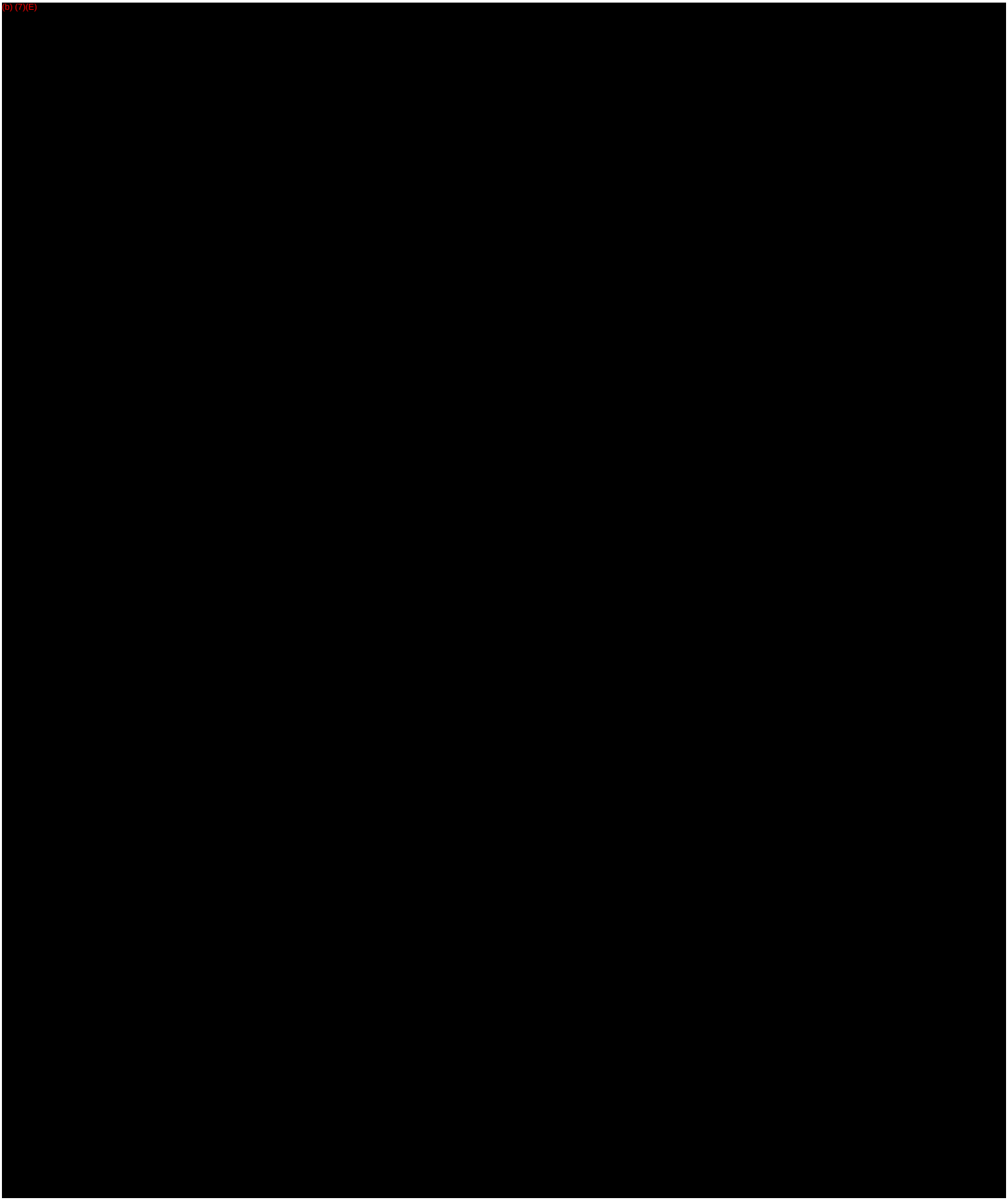

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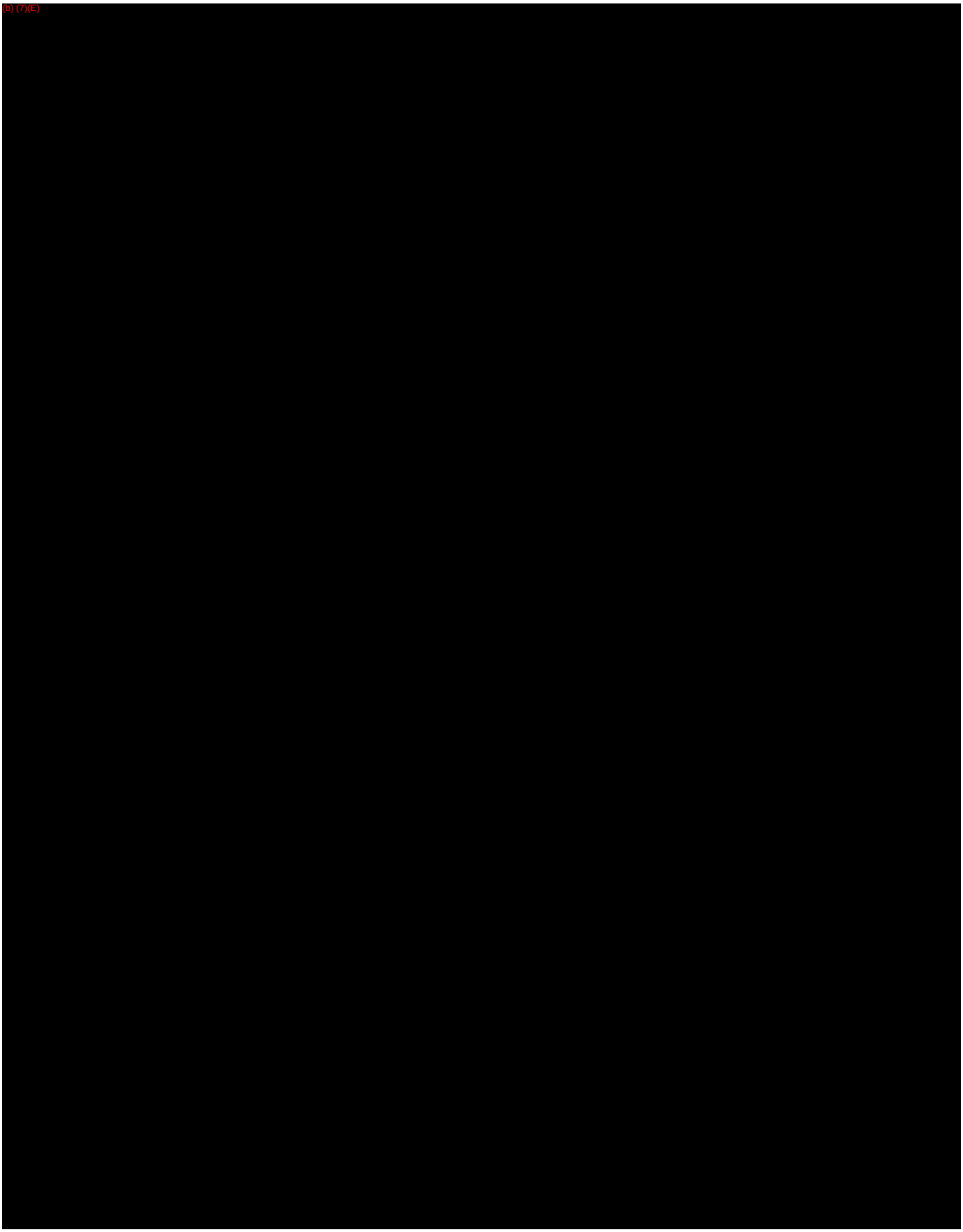

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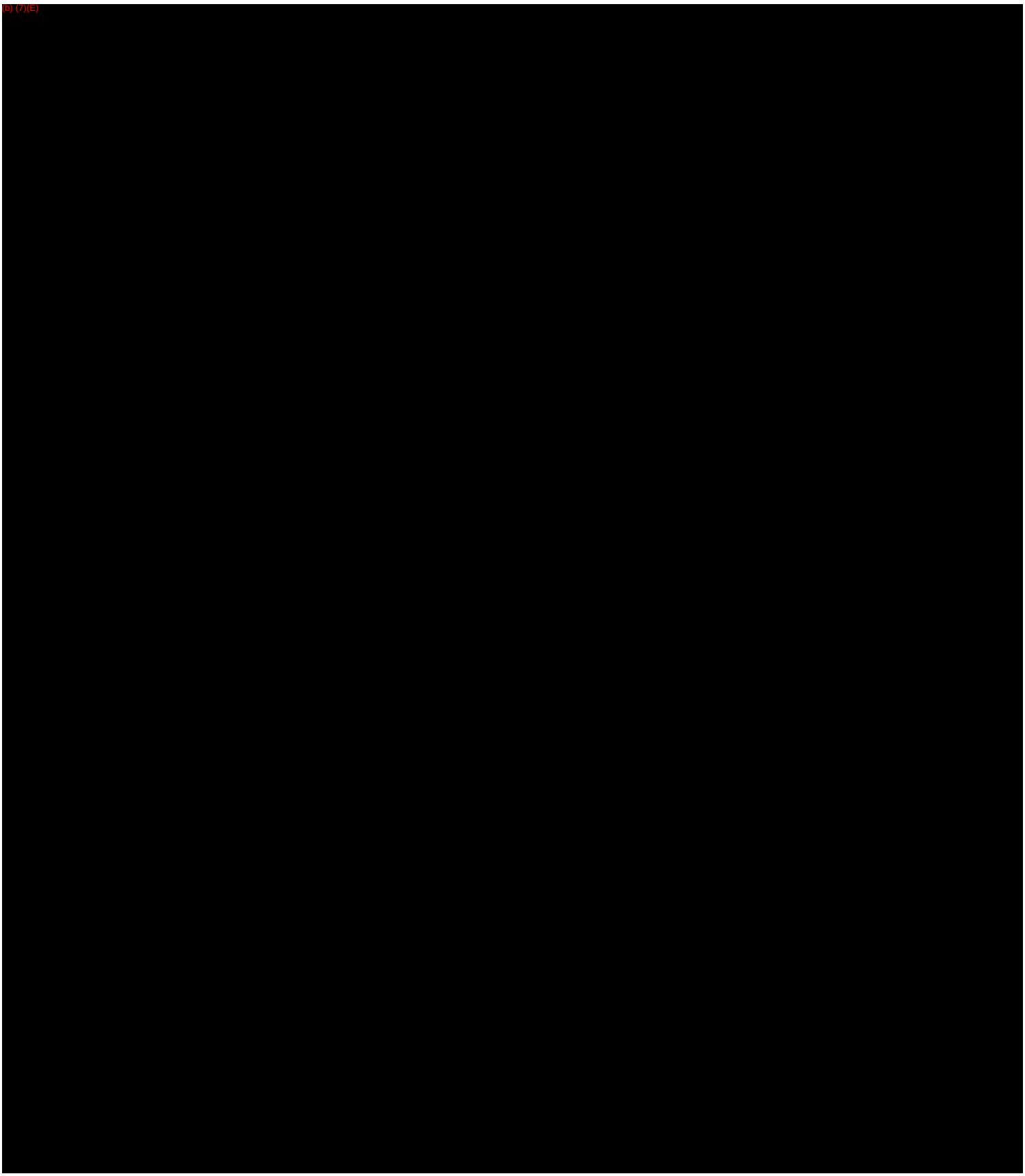

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References

Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), "Mandatory Guidelines for Federal Workplace Drug Testing Programs", Federal Register, April 13, 2004, Volume 69, Number 71 p 19644-19673.

Hawks RL, Chiang CN, eds. *Urine Testing for Drugs of Abuse*. NIDA research monograph 73, National Institute on Drug Abuse (NIDA), Rockville, MD: 1986.

Baselt RC, Cravey RH. *Disposition of Toxic Drugs and Chemical in Man.* 3rd ed. Chicago, IL: Year Book Medical Publishers Inc., 1990:780-783.

Ellenhorn MJ, Barceloux DG. *Medical Toxicology*. New York, NY: Elesevier Science Publishing Company, Inc. 1988:675-682.

Wyngarrden JB, Smith LH Jr, eds. *Cecil Textbook of Medicine*. Philadelphia, PA: WB Saunders Co, 1986:52-58.

Kwong TC, et al. Critical issues in urinalysis of abused substances: report of the substance testing committee. *Clin Chem*. 1988; 34/3: 605-632.

Emit® II Plus Cannabinoid Assay package insert. Siemens Healthcare Diagnostics, Inc. Newark, DE. 2008-03. 9N022UL.9DS_US_B.

ETHYL ALCOHOL ASSAY

Introduction and Principle

Alcohol (ethyl alcohol, ethanol) determination is the most frequently performed medico-legal test, and ethanol is the most common toxic substance encountered. In addition to beverages, products containing alcohol in significant amounts include mouthwashes, colognes, and medicinal preparations. Measurements of ethanol levels are used to determine legal impairment for forensic purposes, in the diagnosis and treatment of alcohol dependency, and, in emergency settings, to detect alcohol poisoning.

Ethanol's deleterious effects are well documented. It has been linked with birth defects (fetal alcohol syndrome), cardiac conditions, high blood pressure, liver disease, and mental deterioration. It is by far the leading cause of death from hepatic failure. Additionally, ethanol-induced behavior is a contributing factor in the majority of accidents and murders.

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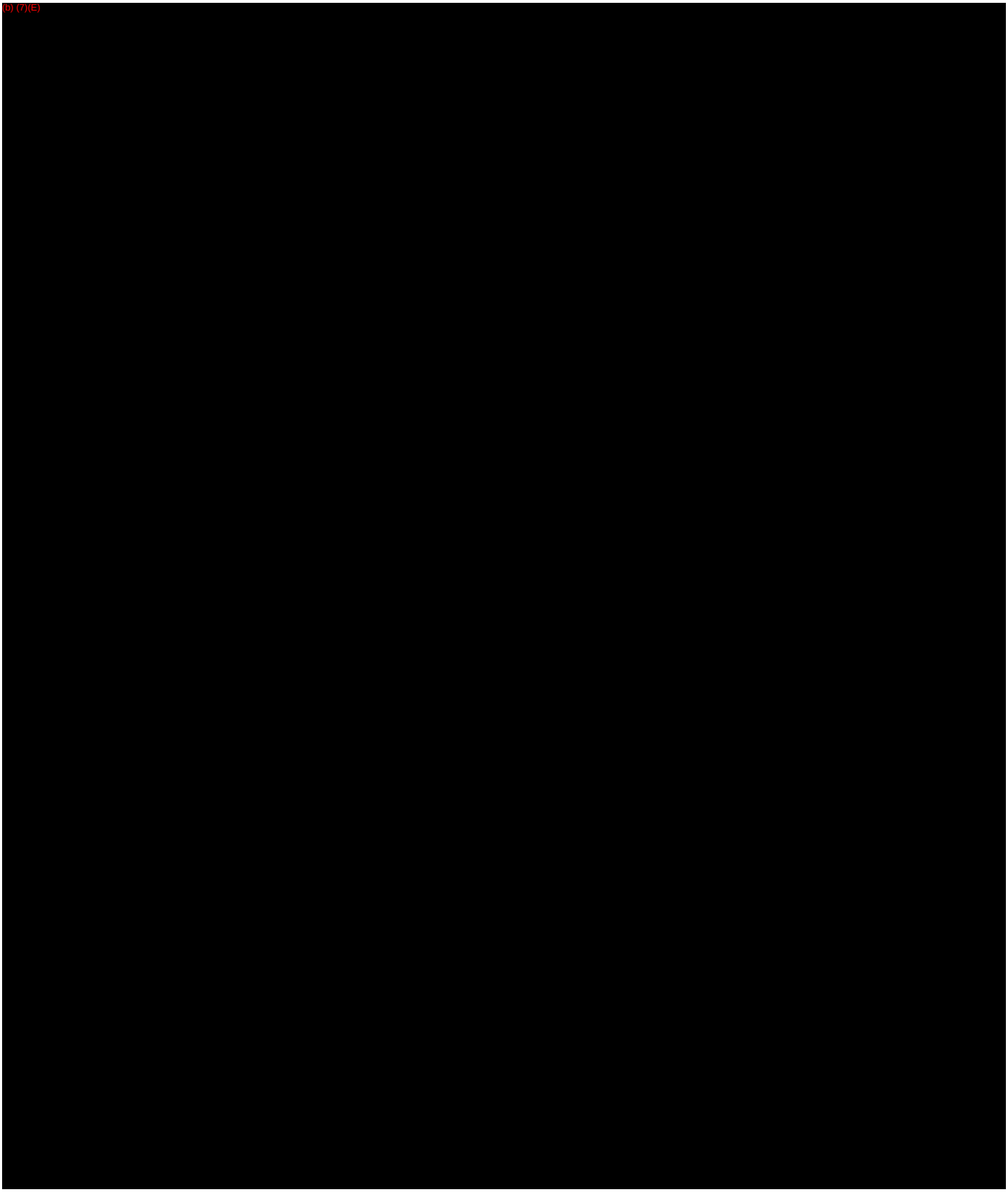

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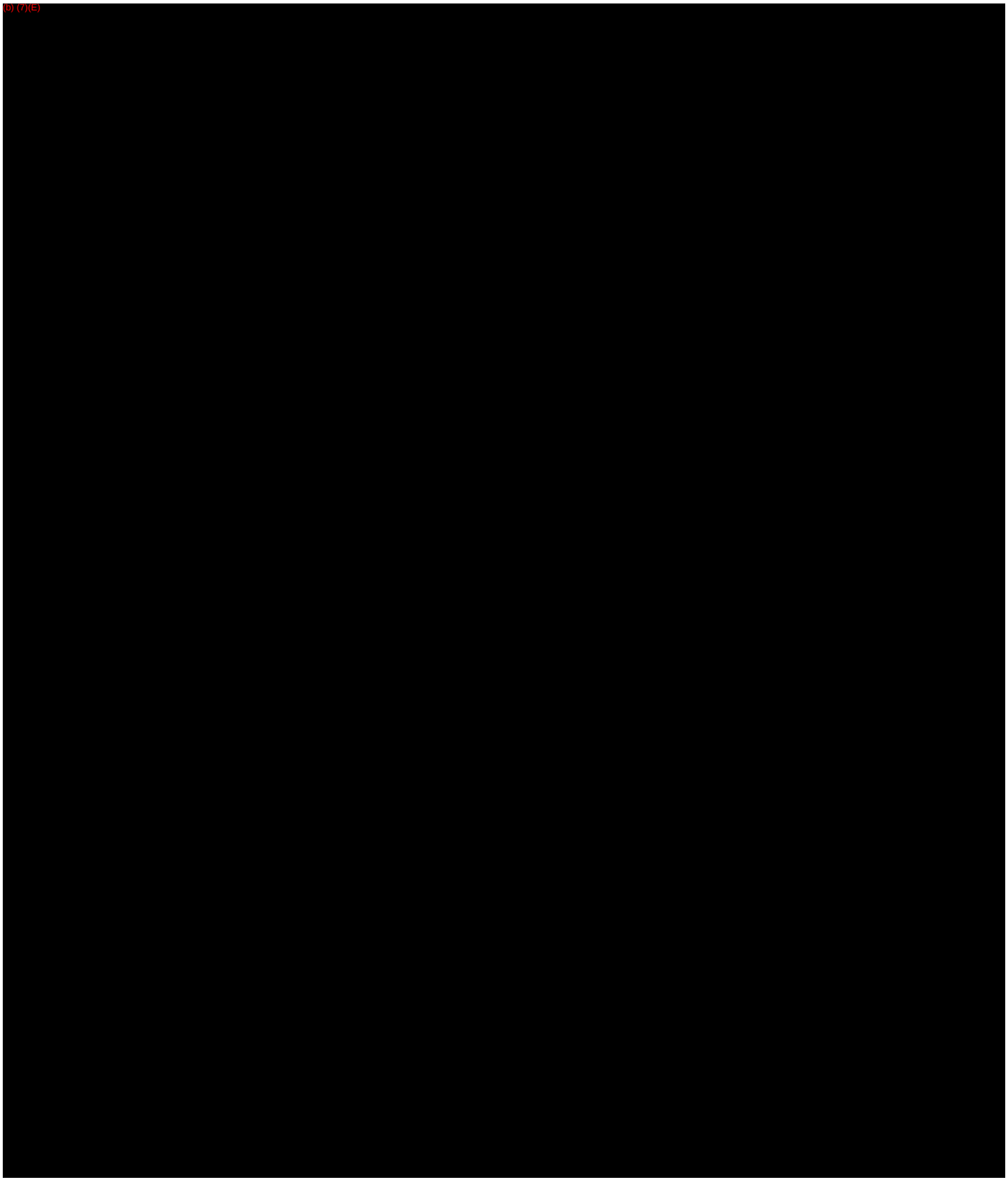

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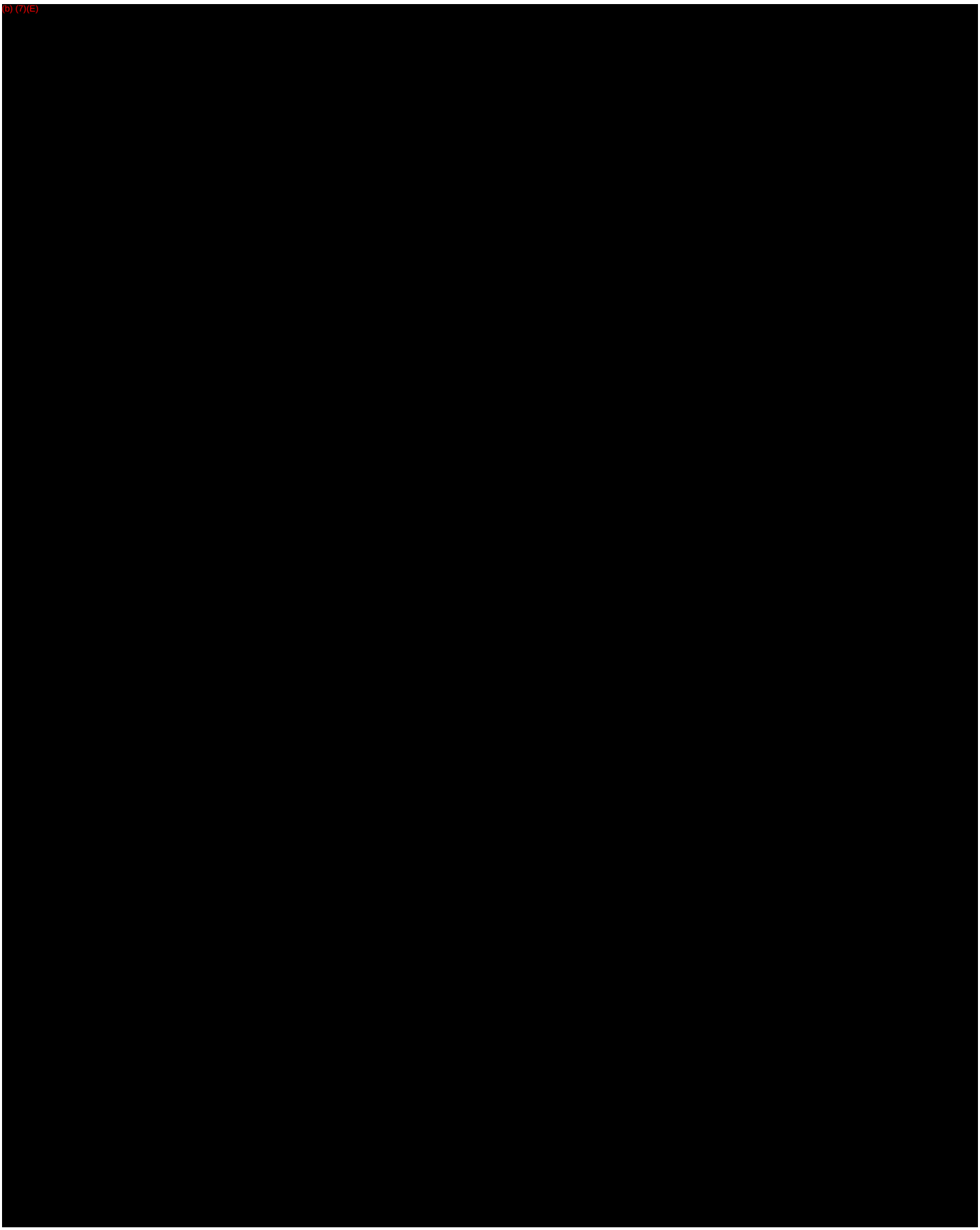

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References

Baselt RC. *Disposition of Toxic Drugs and Chemicals in Man*. 3rd ed. Chicago, IL: Year Book Medical Publishers, Inc; 1989, pp 322-234

Ellenhorn MJ, Barceloux DG. *Medical Toxicology*. New York, NY: Elsevier Science Publishing Company, Inc, 1988, pp 525-6 and 782-796.

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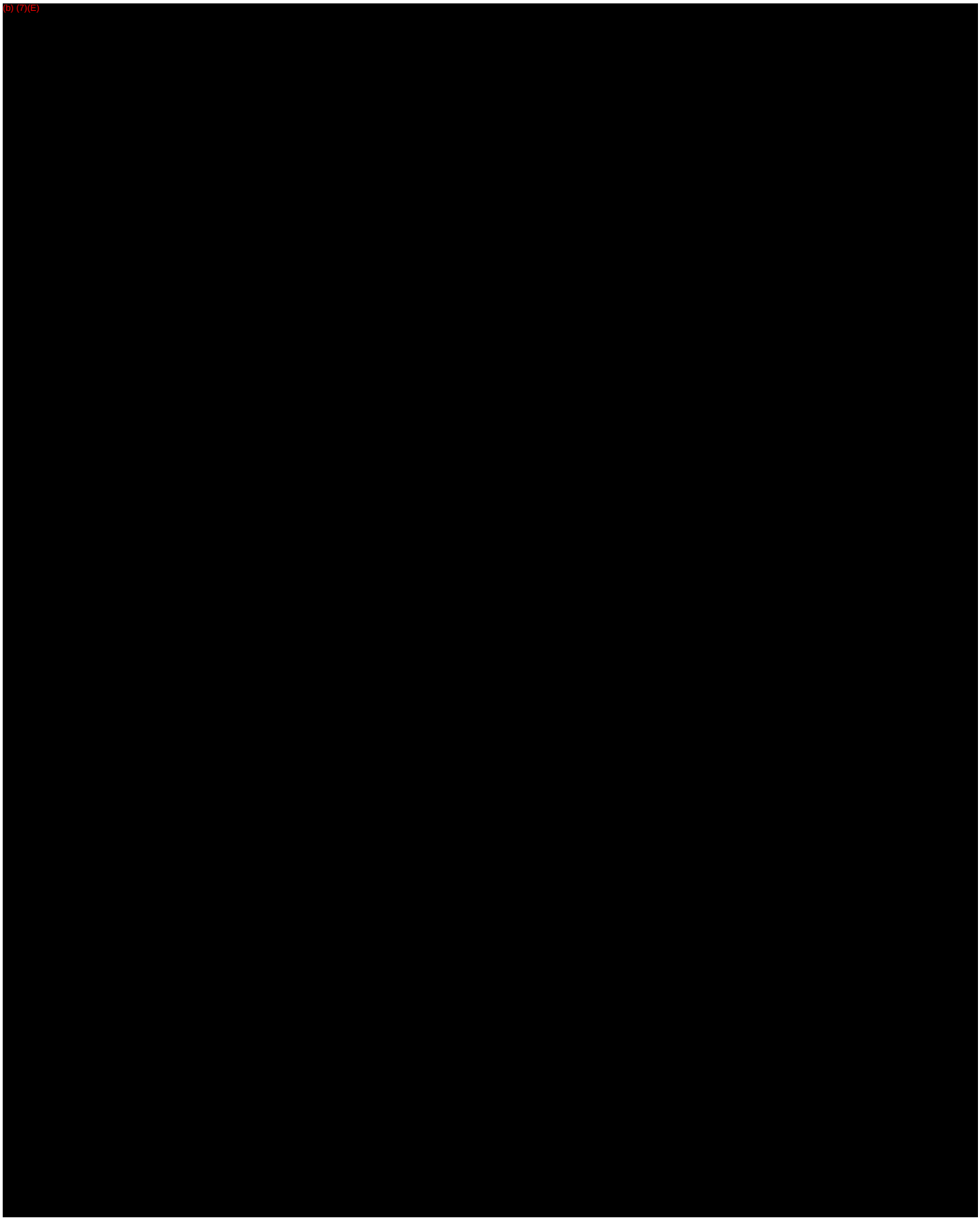

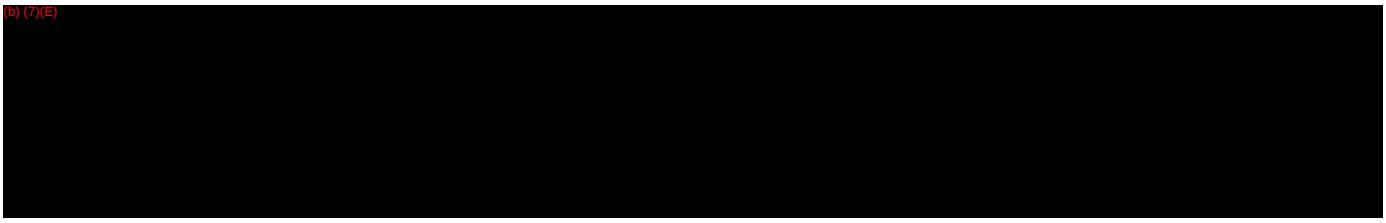
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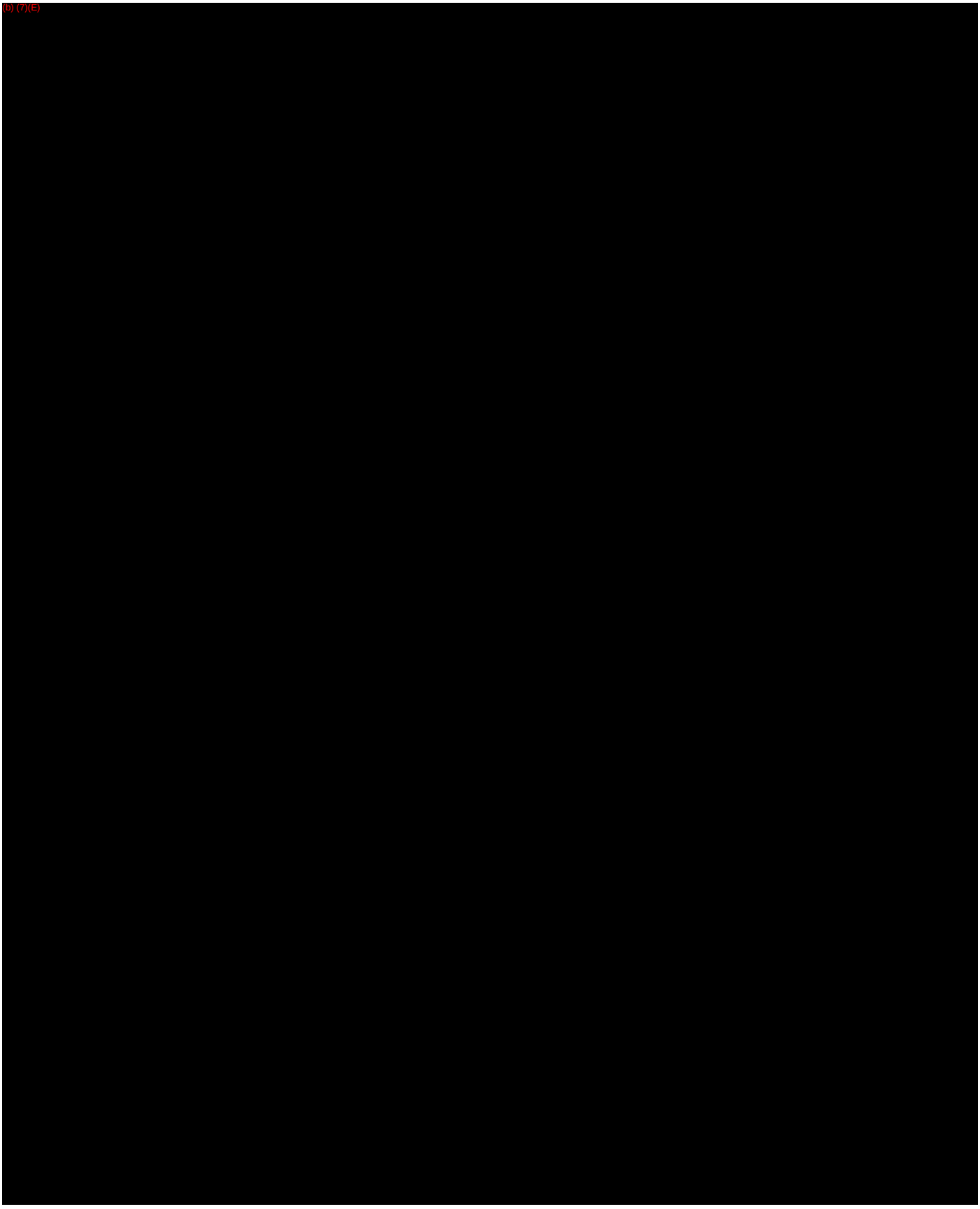

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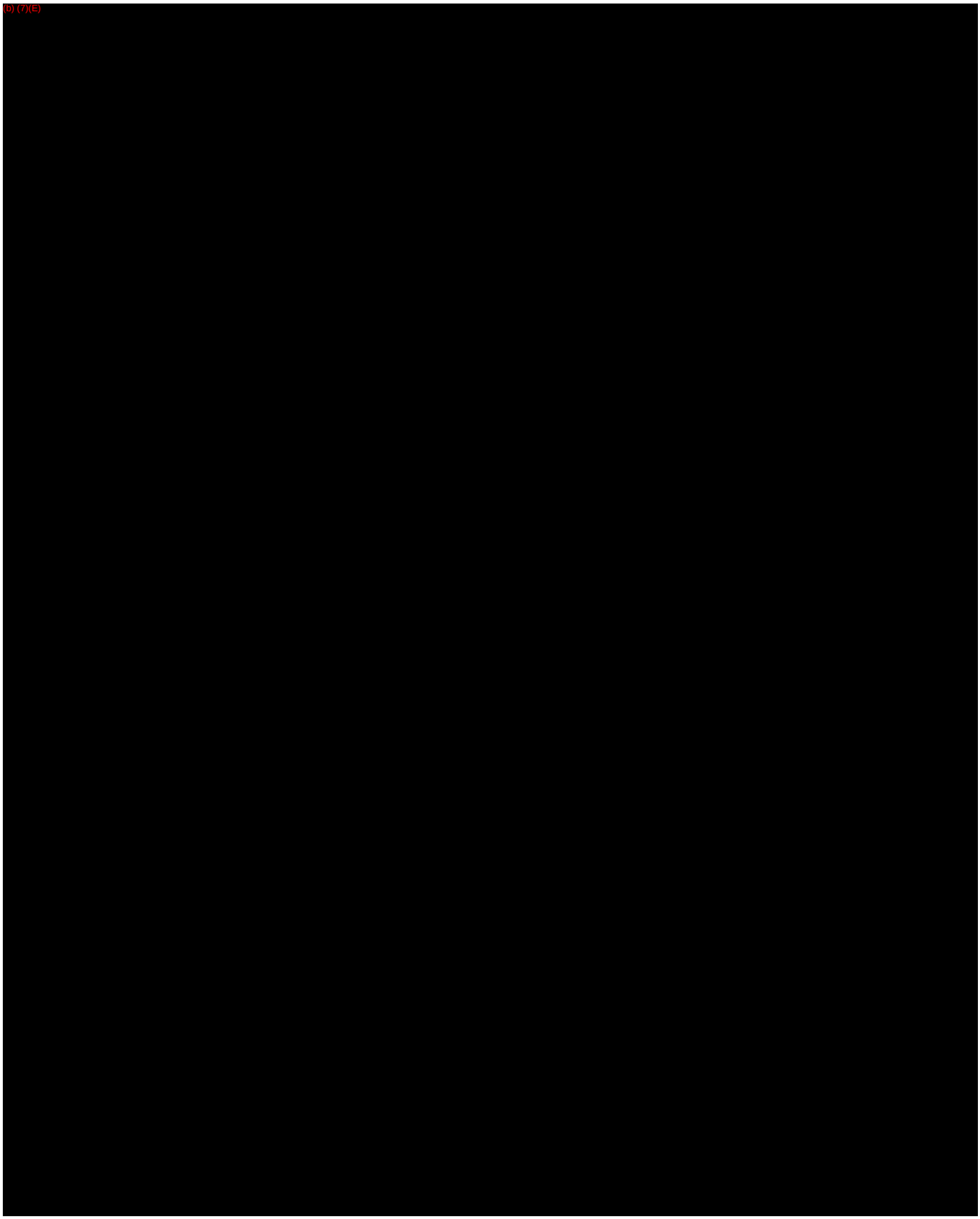

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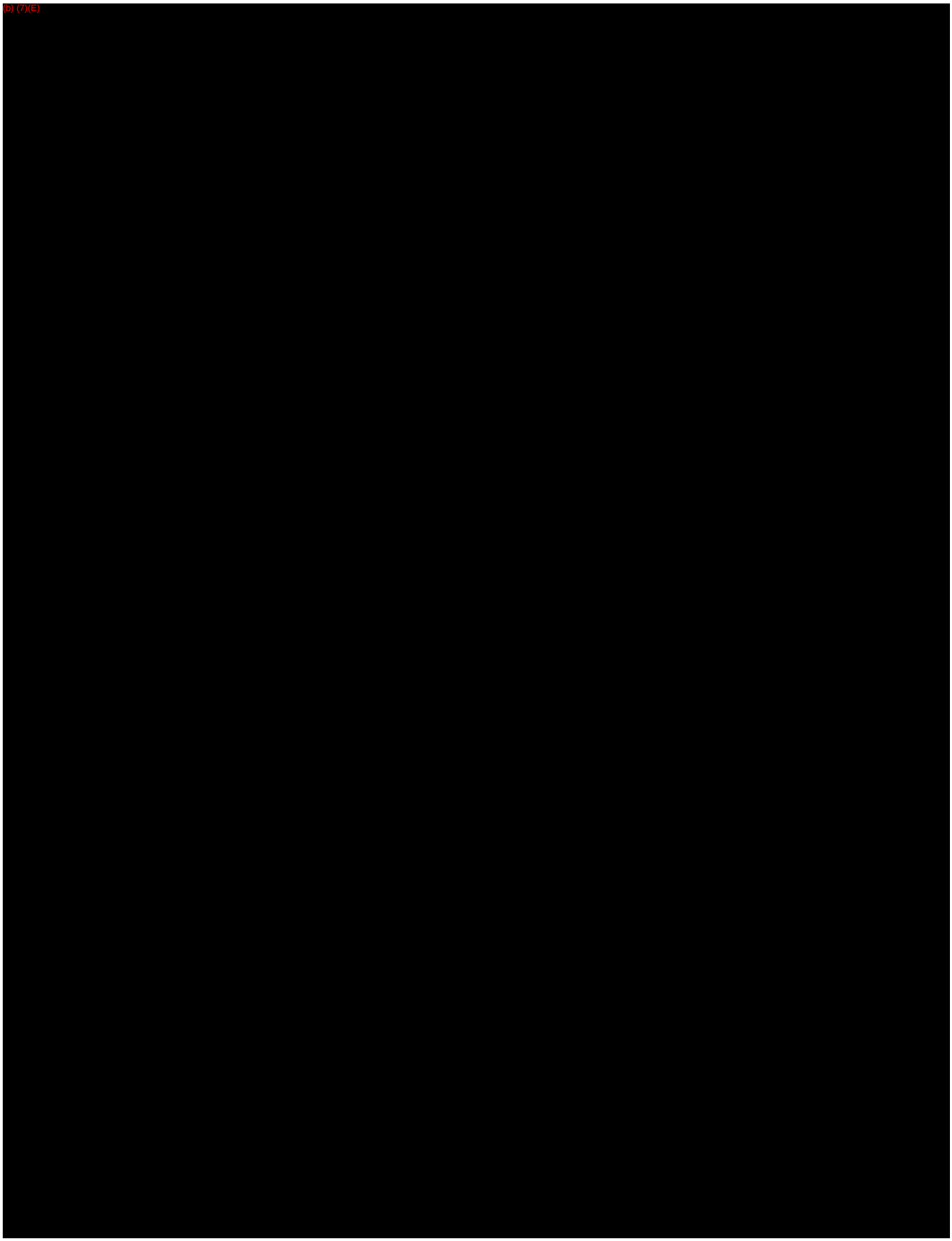

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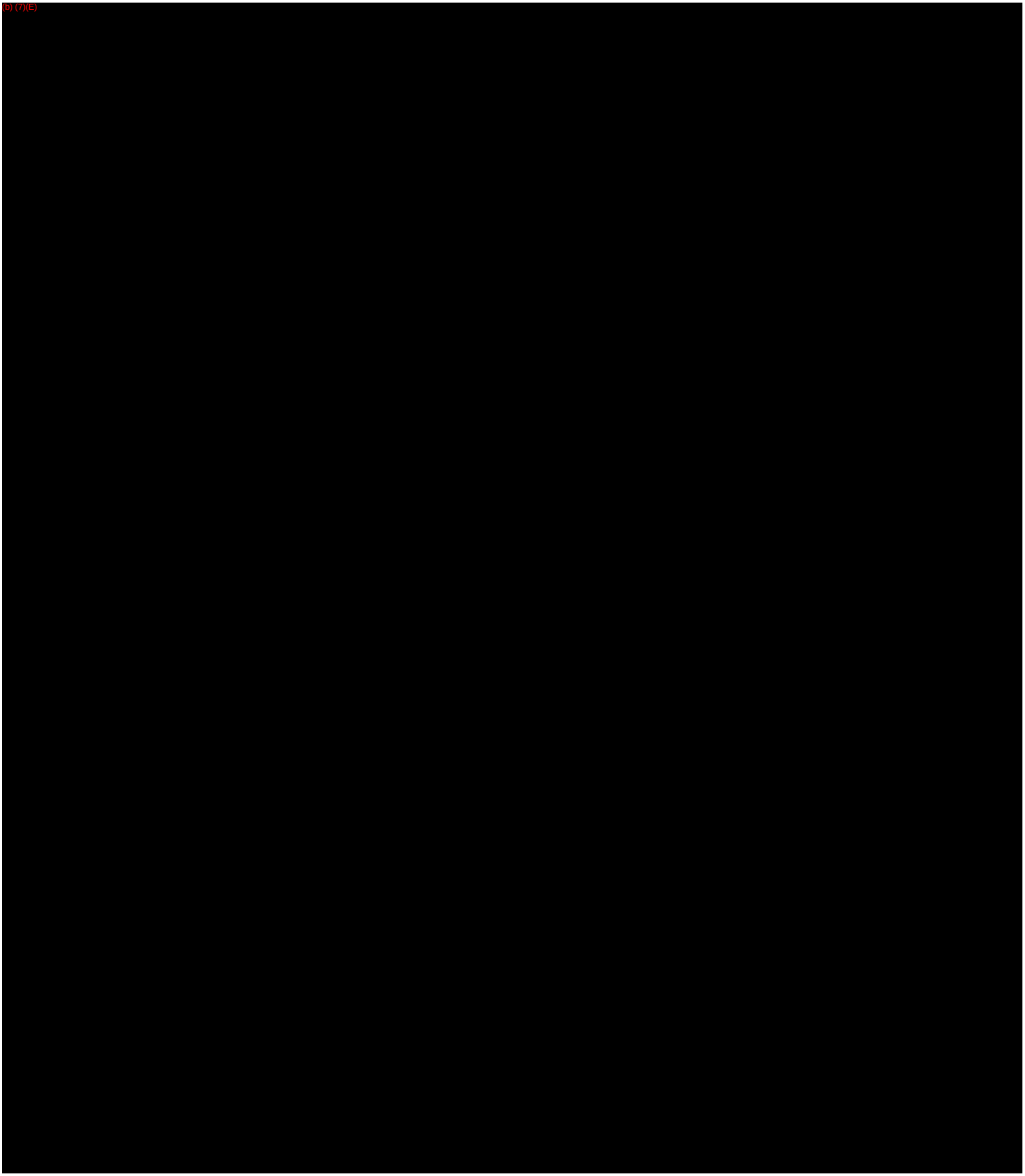


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References

1. Hawks RL, Chiang CN, eds. *Urine Testing for Drugs of Abuse*. Rockville, MD: National Institute on Drug Abuse (NIDA), Department of Health and Human Services; 1986. NIDA research monograph 73.

2. Baselt, R.C. *Disposition of Toxic Drugs and Chemicals in Man*, Biomedical Publications, 4th Ed. 1995.

3. Giannini AJ. Phencyclidine. In: Giannini AJ, Slaby AE, eds. Drugs of Abuse. Oradell, NJ: Medical Economics Books; 1989.

4. Aniline O, Pitts FN. Phencyclidine (PCP): A review and perspectives. *CRC Crit Rev Toxicol*. 1982; 10:145-177.

5. Marwah J, Pitts DK. Psychopharmacology of phencyclidine. In: Clouet DH, ed. Phencyclidine: An Update. NIDA Research Monograph. 1986; 64:127-133.

6. Busto U, Bendayan R, Sellers EM. Clinical pharmacokinetics of non-opiate abused drugs. Clin Pharmacokinetics. 1989; 16:1-26.

7. Jerrard DA. Designer drugs - A current perspective. J Emer Med. 1990;8:733-741.

8. Henderson DR, Friedman SB, Harris JD, et al. CEDIA®, a new homogeneous immunoassay system. Clin Chem. 1986; 32:1637-1641.

9. *Mandatory Guidelines for Federal Workplace Drug Testing Programs*. Federal Register. 1994; 110 (June 9):11983.

10. Data on traceability are on file at Microgenics Corporation, a part of Thermo Fisher Scientific.

11. Data on file at Microgenics Corporation, a part of Thermo Fisher Scientific.

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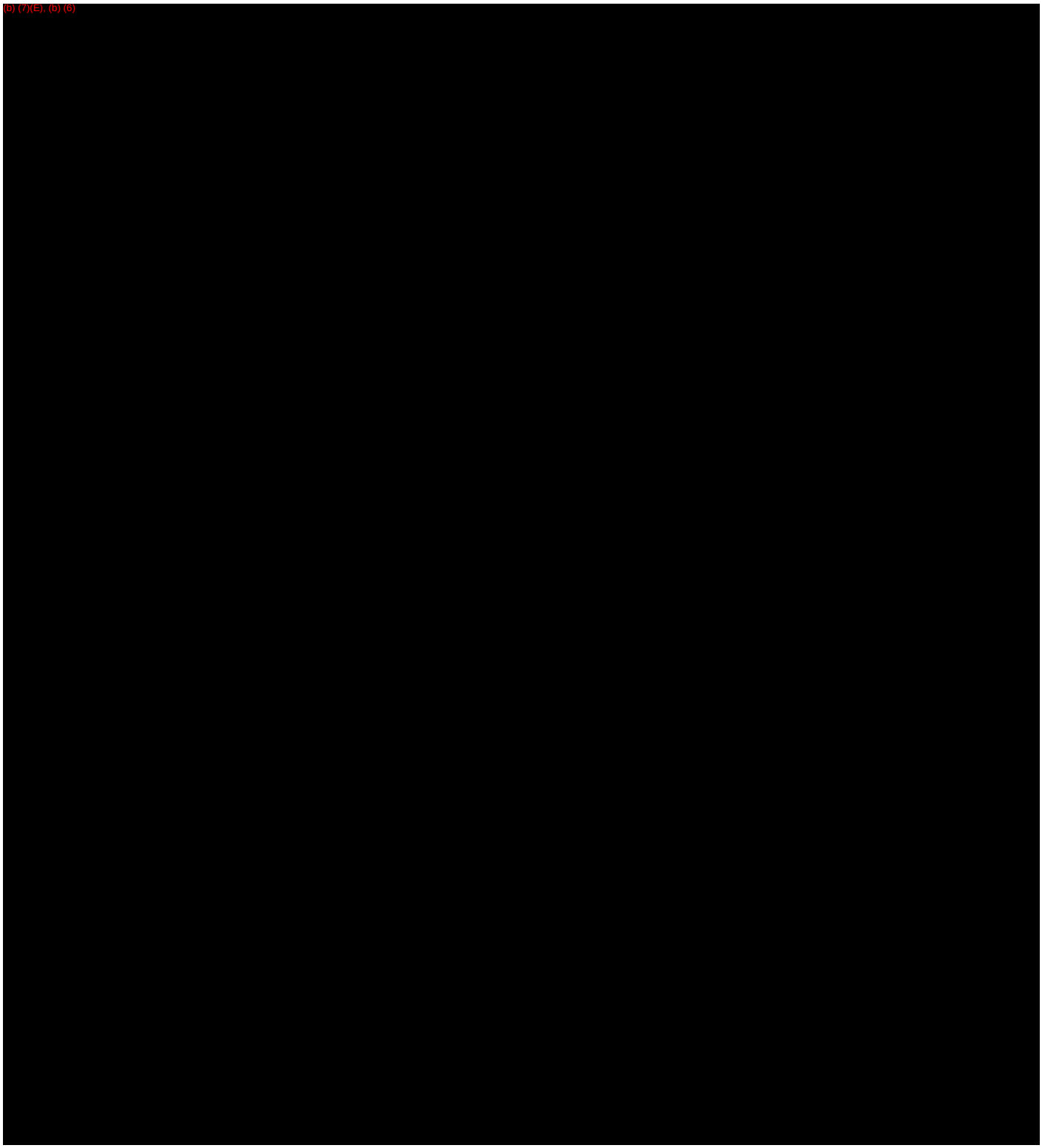

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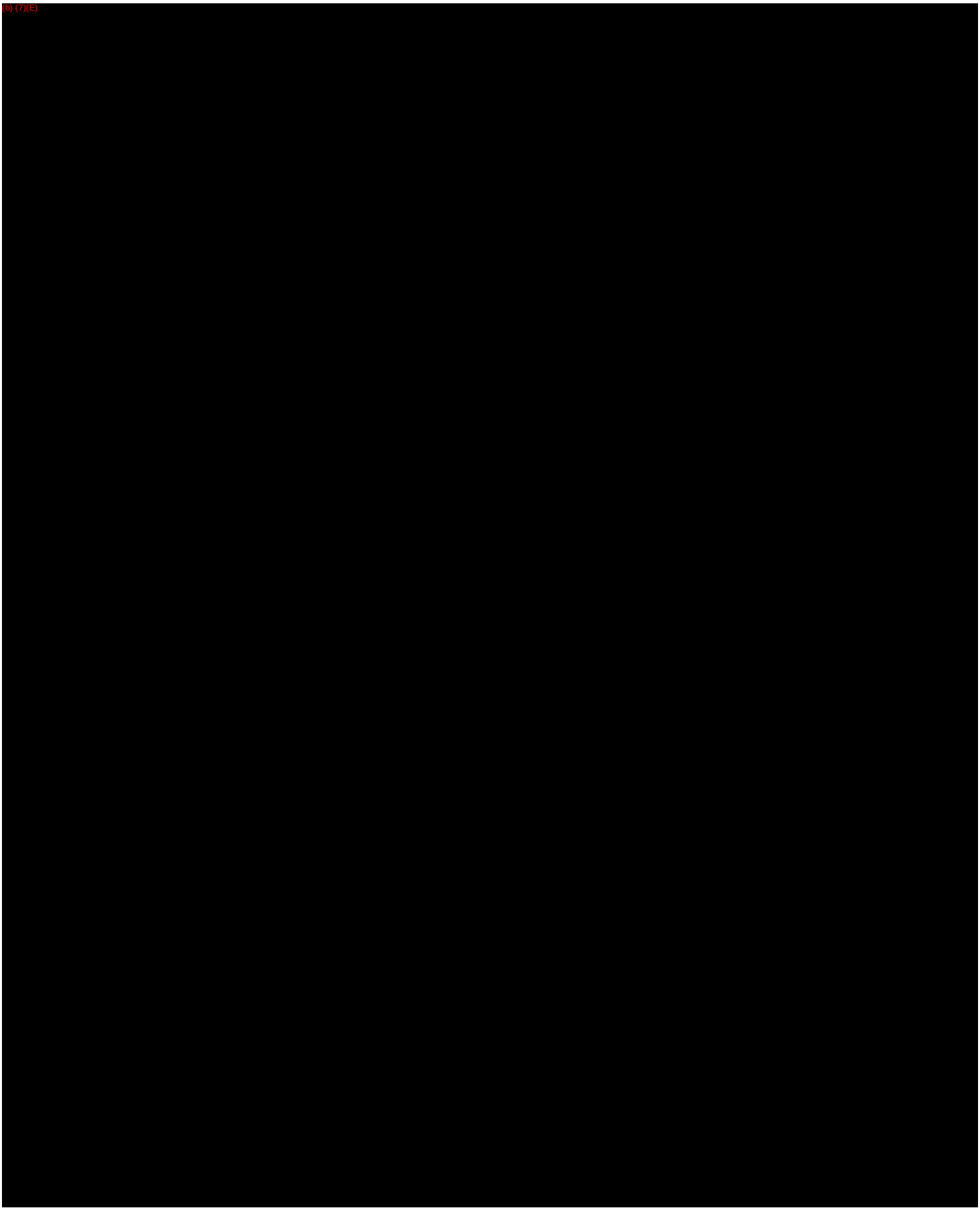

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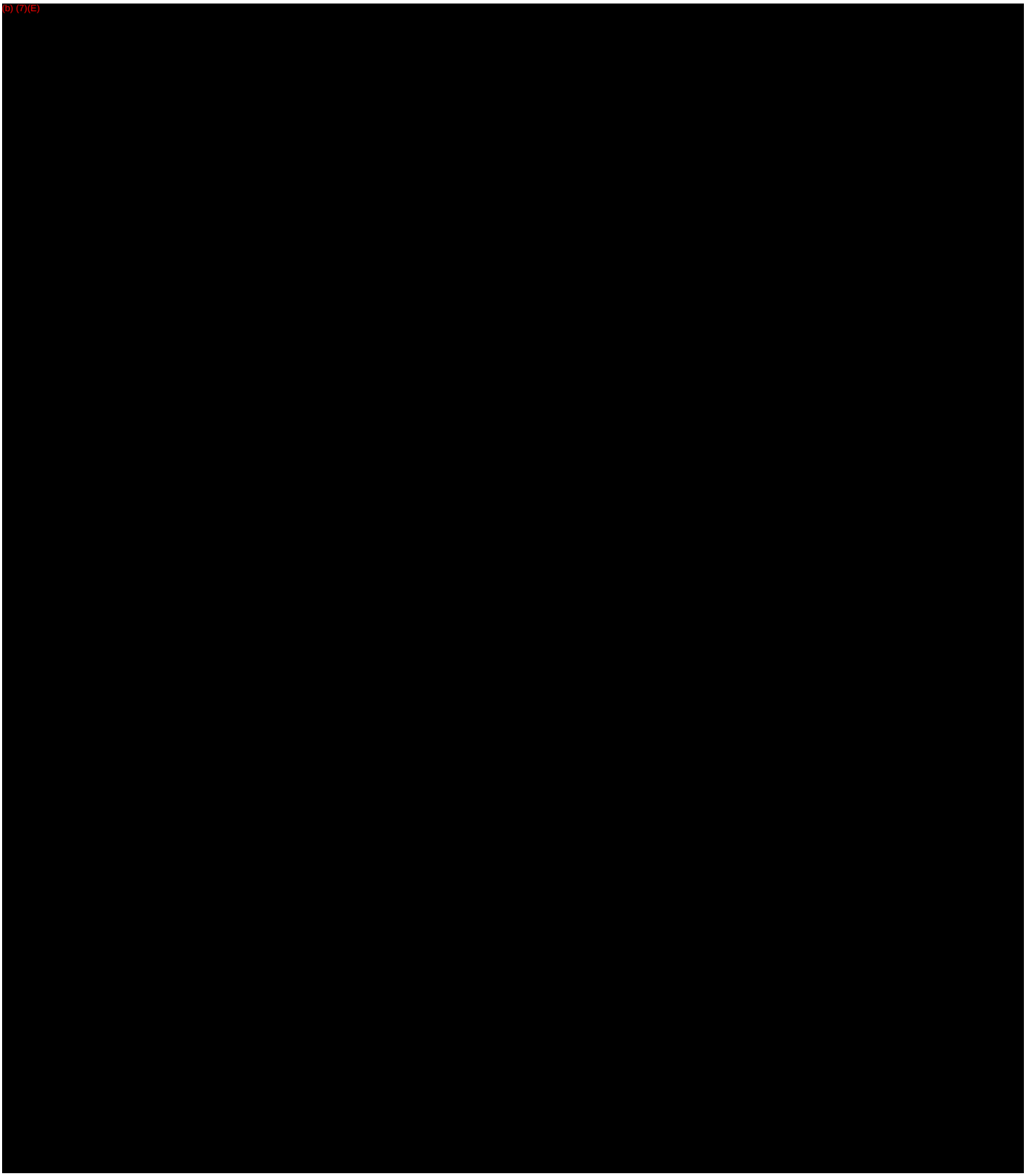

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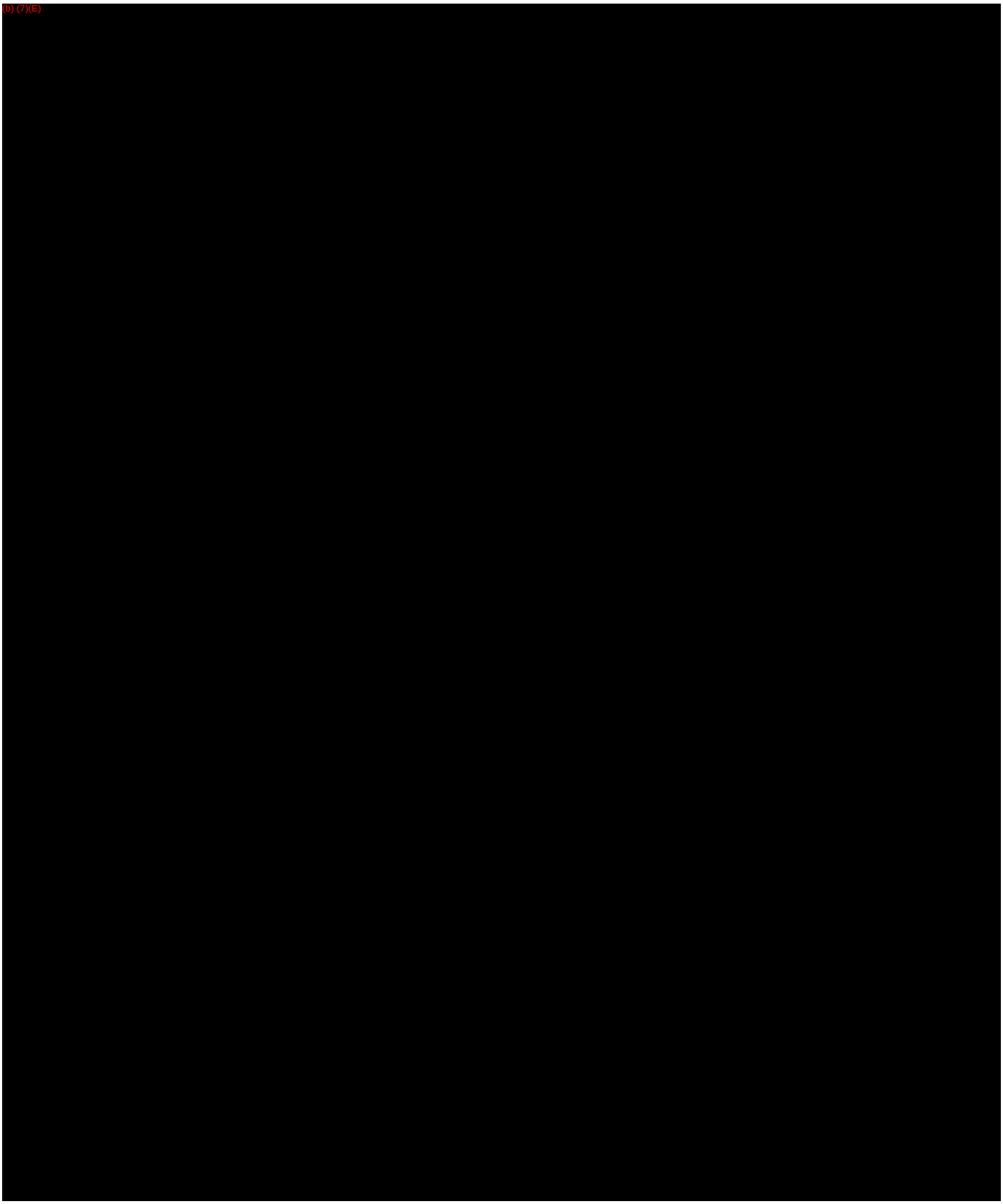

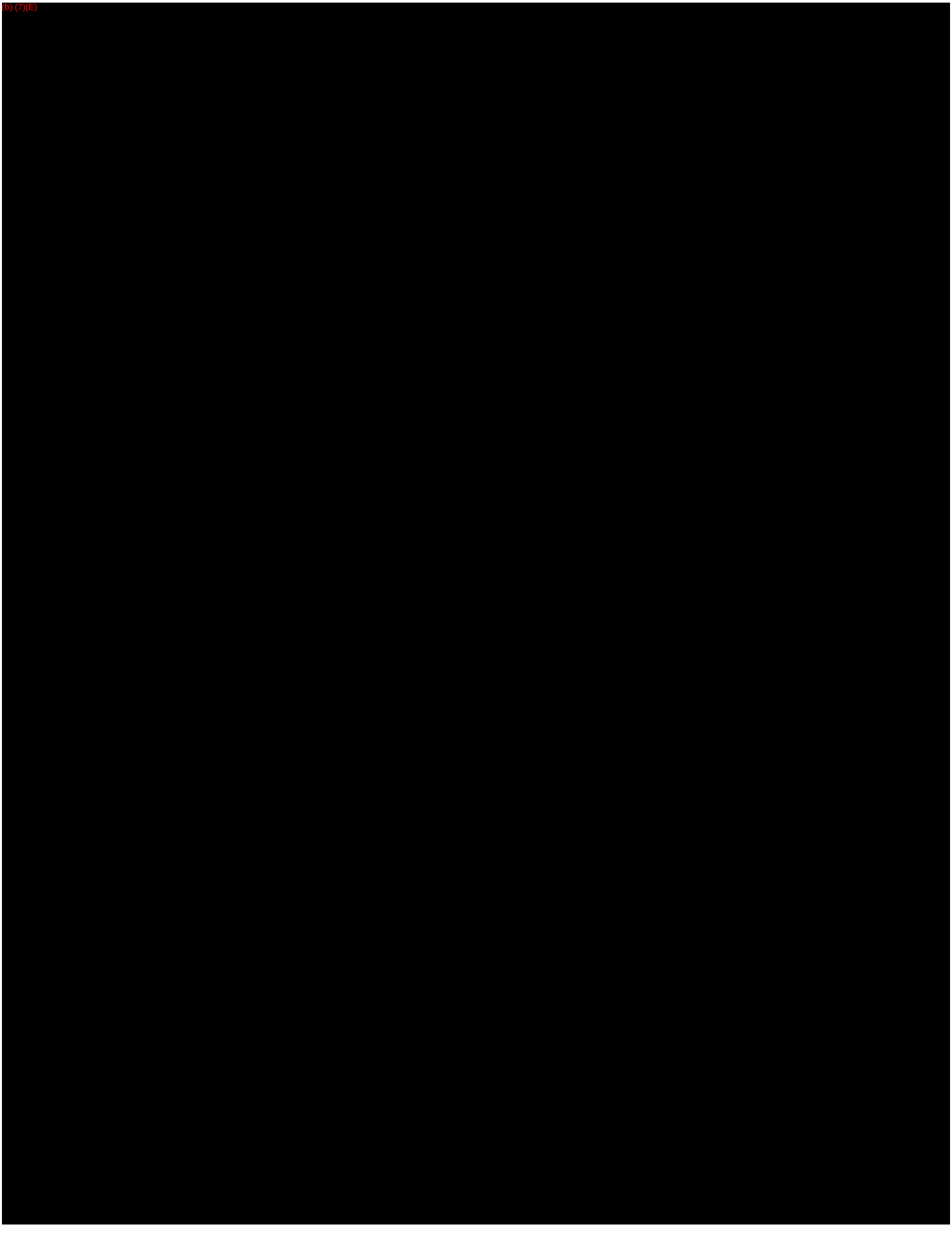
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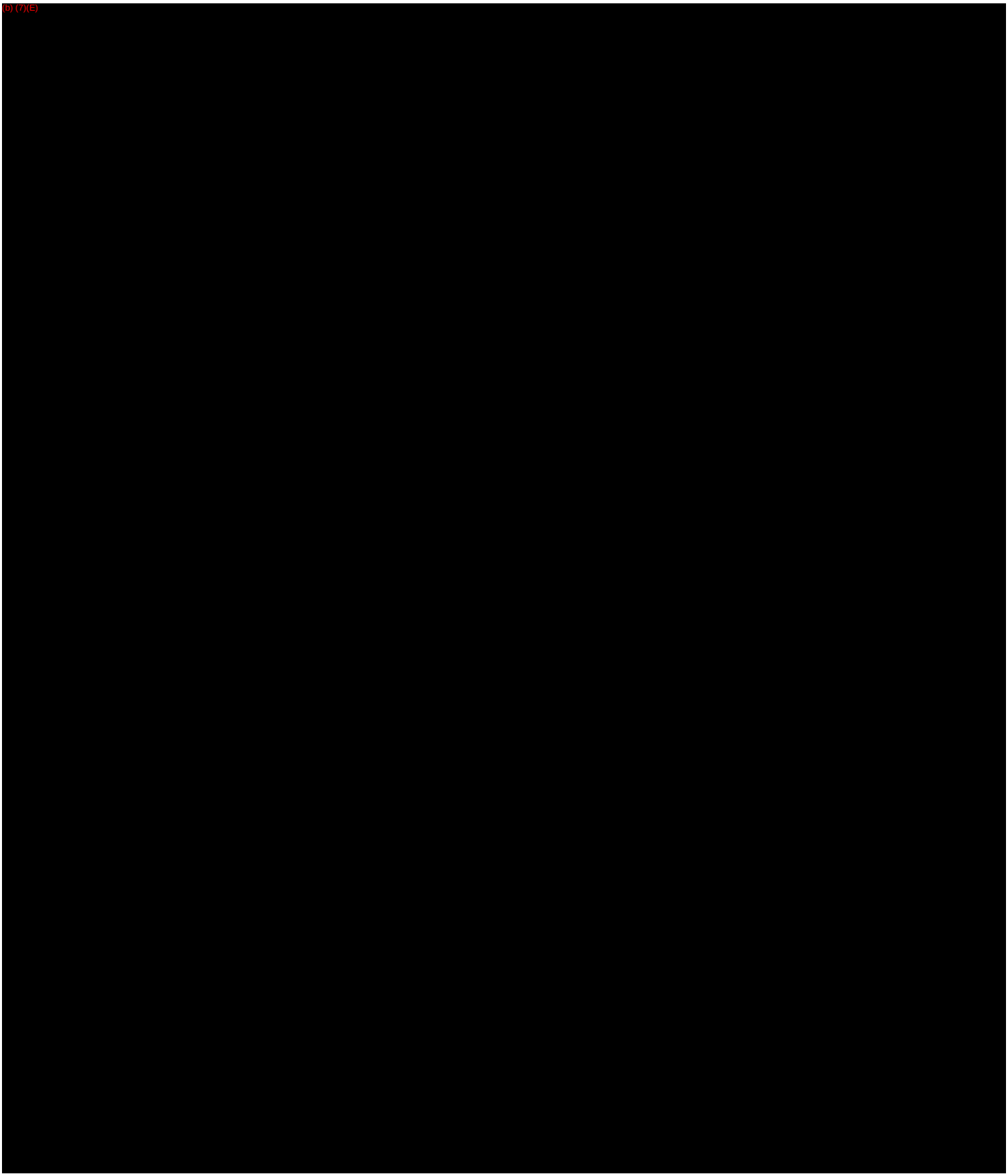

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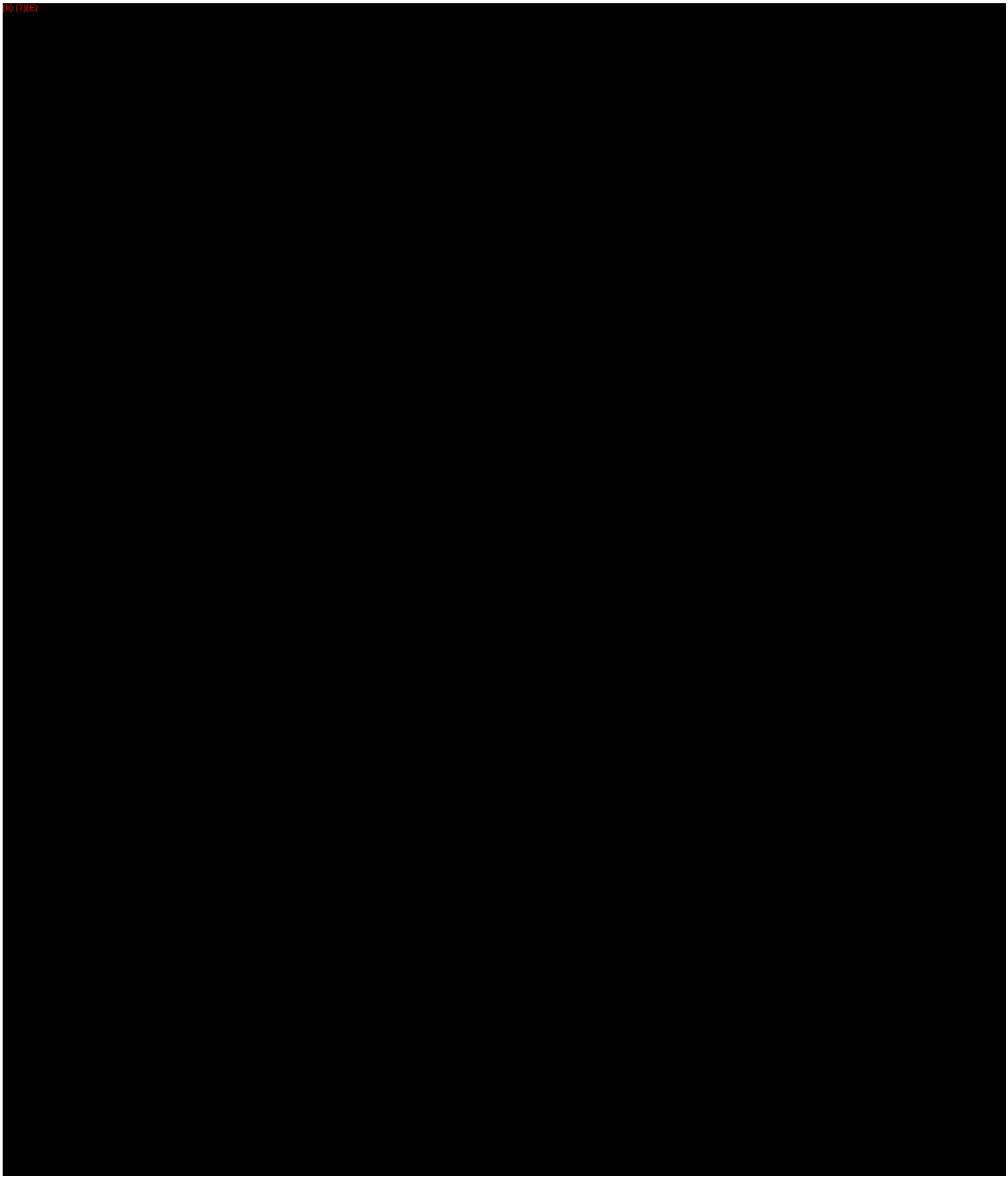

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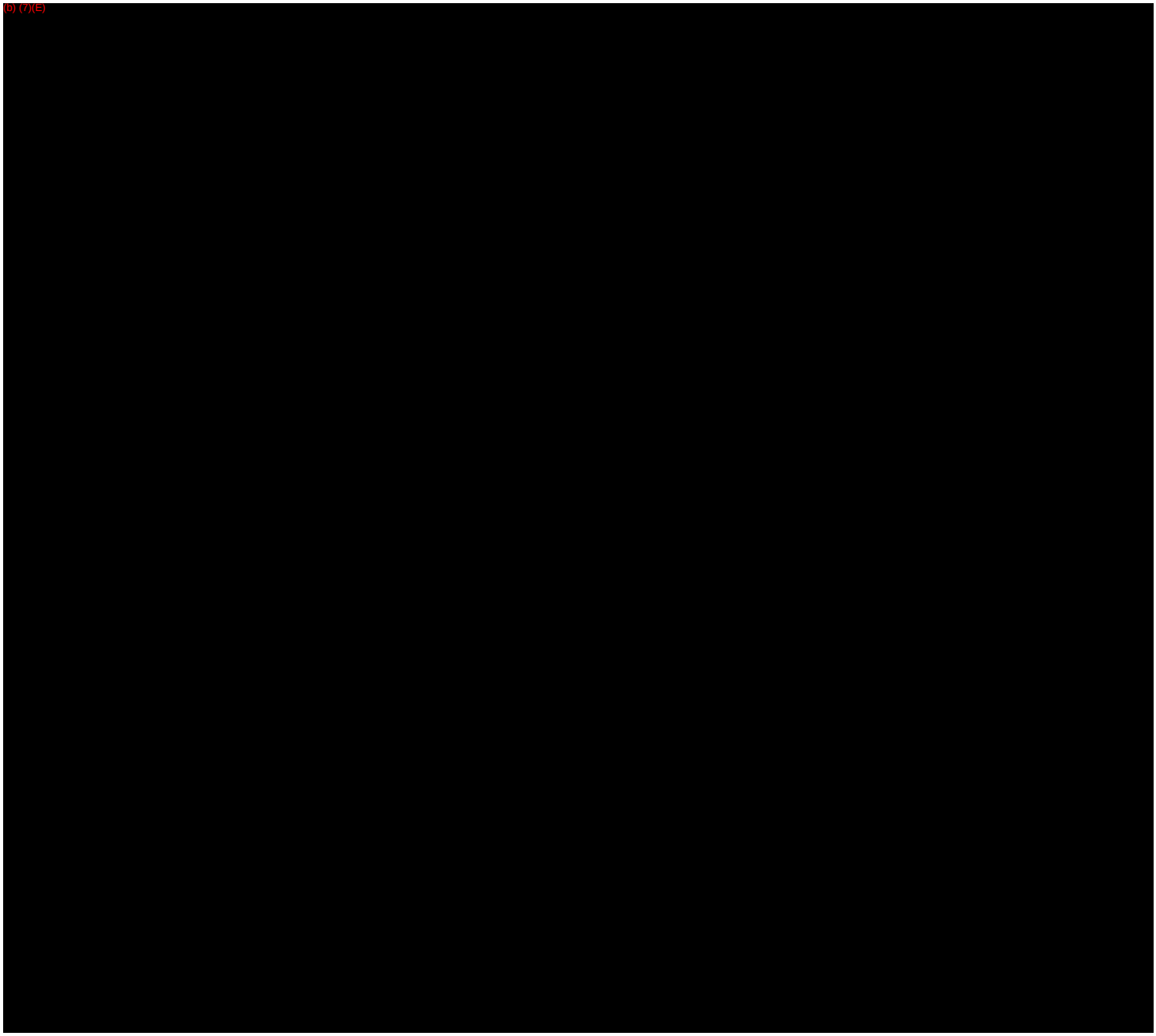

References

Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), "Mandatory Guidelines for Federal Workplace Drug Testing Programs", Federal Register, October 1, 2010, Volume 73, Number 228 p 71858-71907.

Hawks RL, Chiang CN, eds. *Urine Testing for Drugs of Abuse*. NIDA research monograph 73, National Institute on Drug Abuse (NIDA), Rockville, MD: 1986.

Holler, J, et al. Comparison of the Microgenics CEDIA heroin metabolite (6-AM) and the Roche Abuscreen ONLINE opiate immunoassays for the detection of heroin use in forensic urine sampels. *J.Anal. Toxicol*. 2004: 28:489-493.


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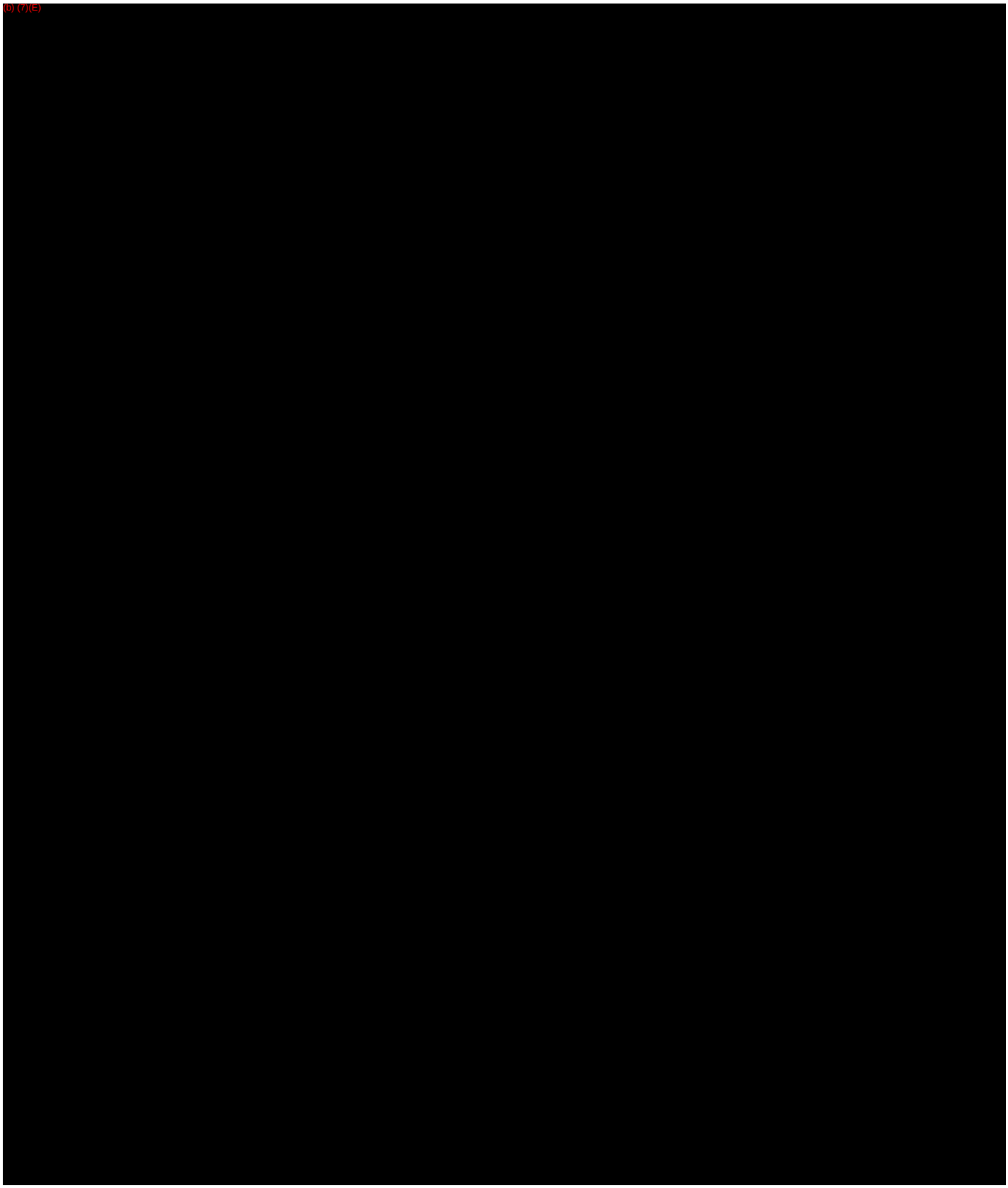
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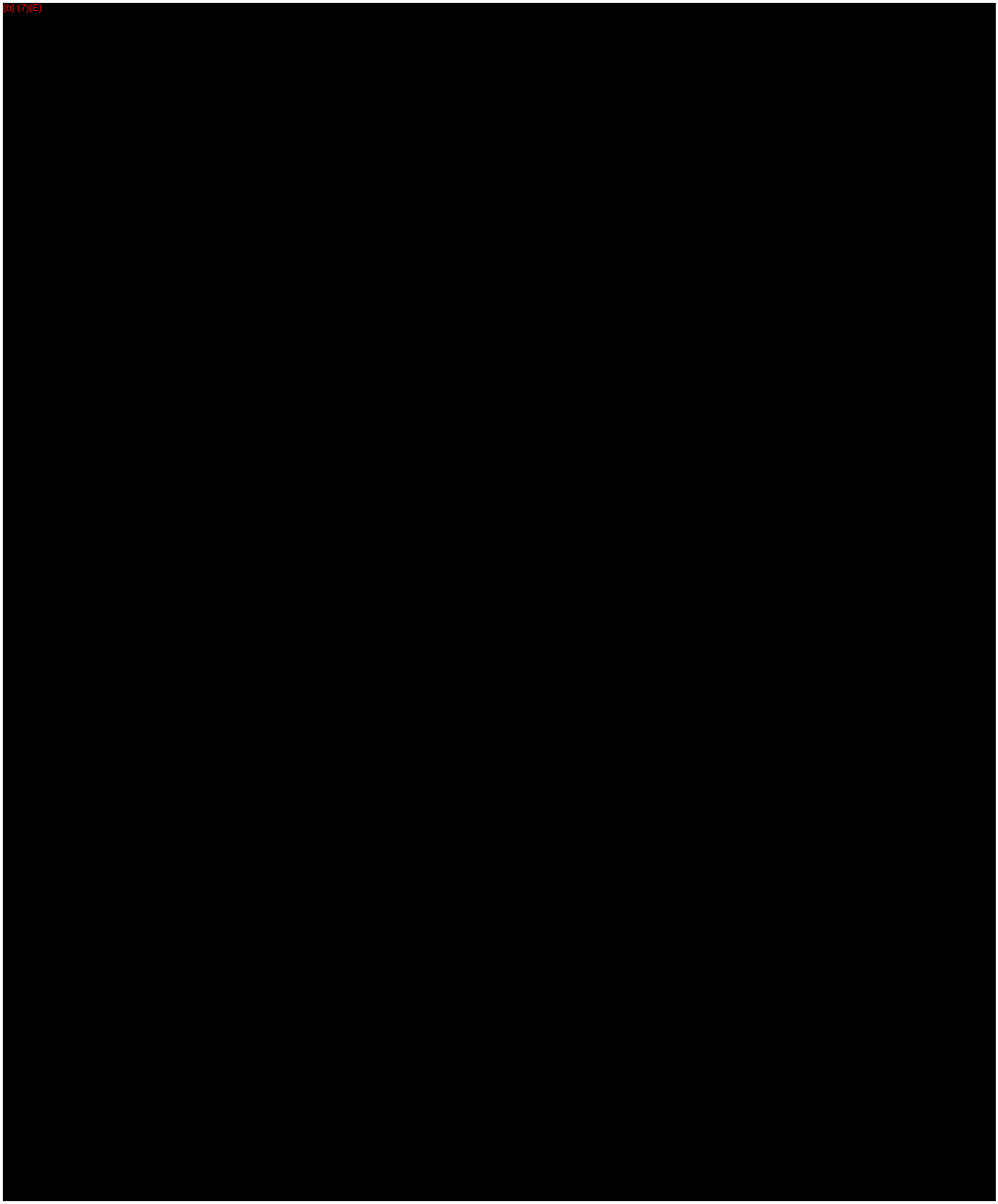


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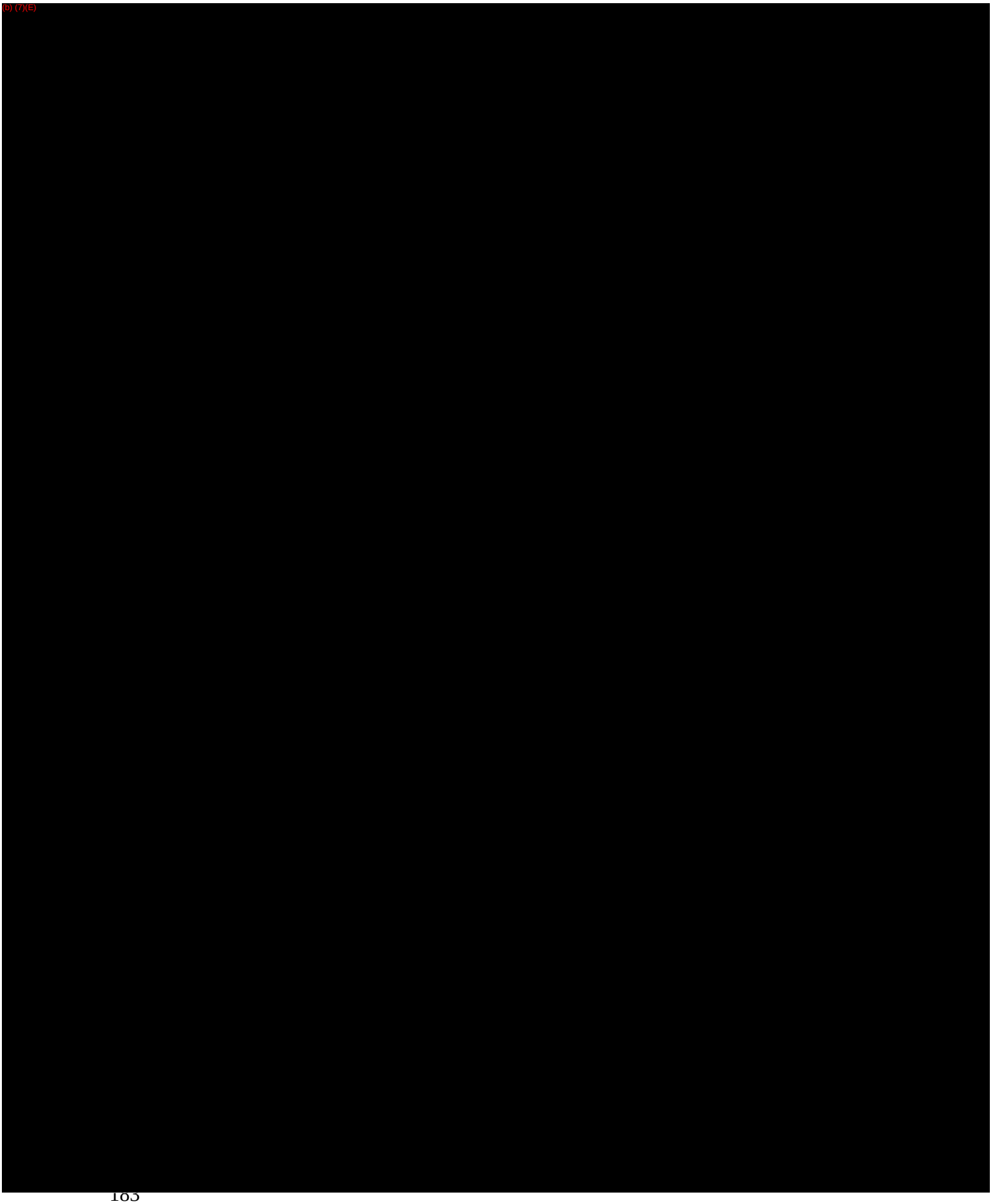

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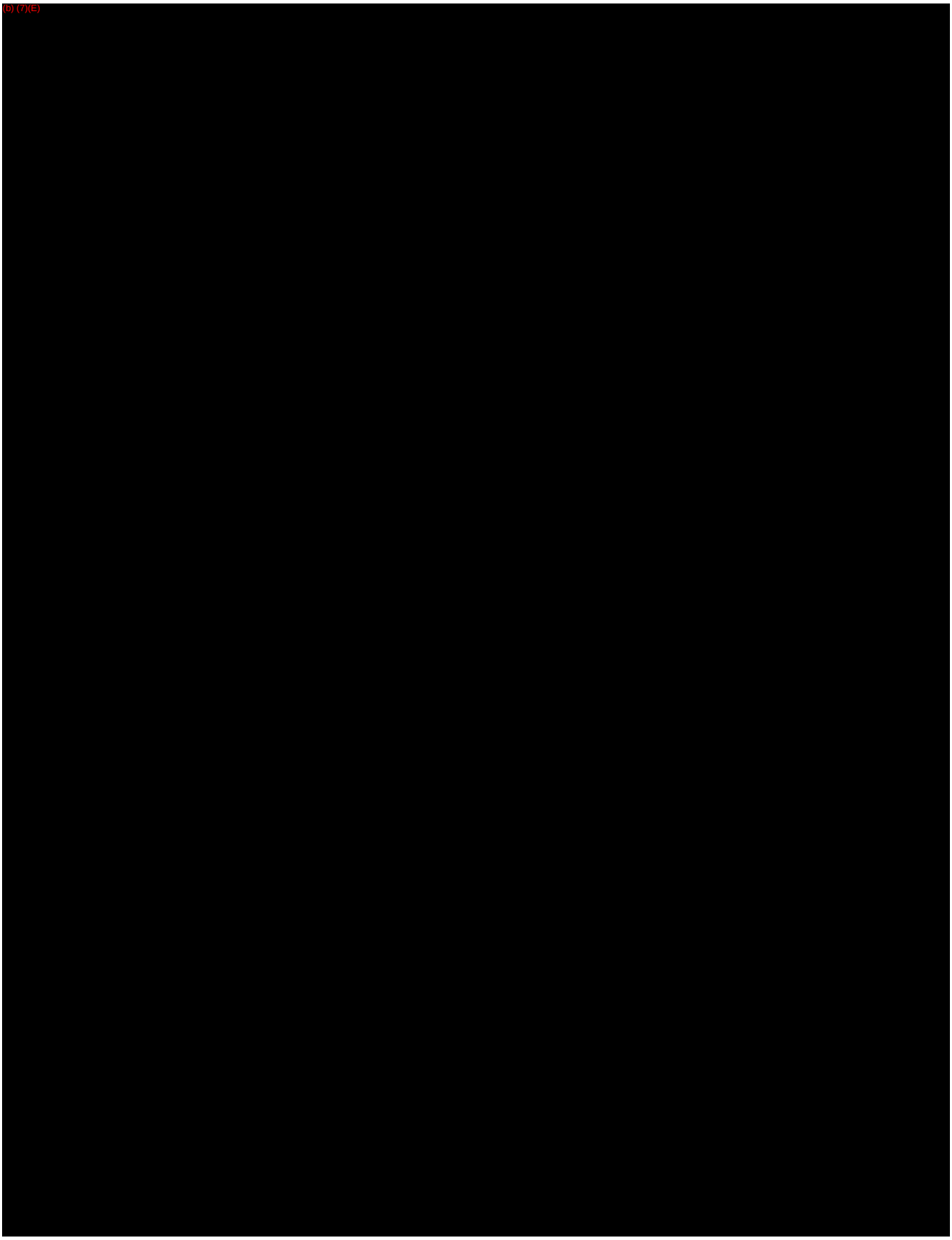
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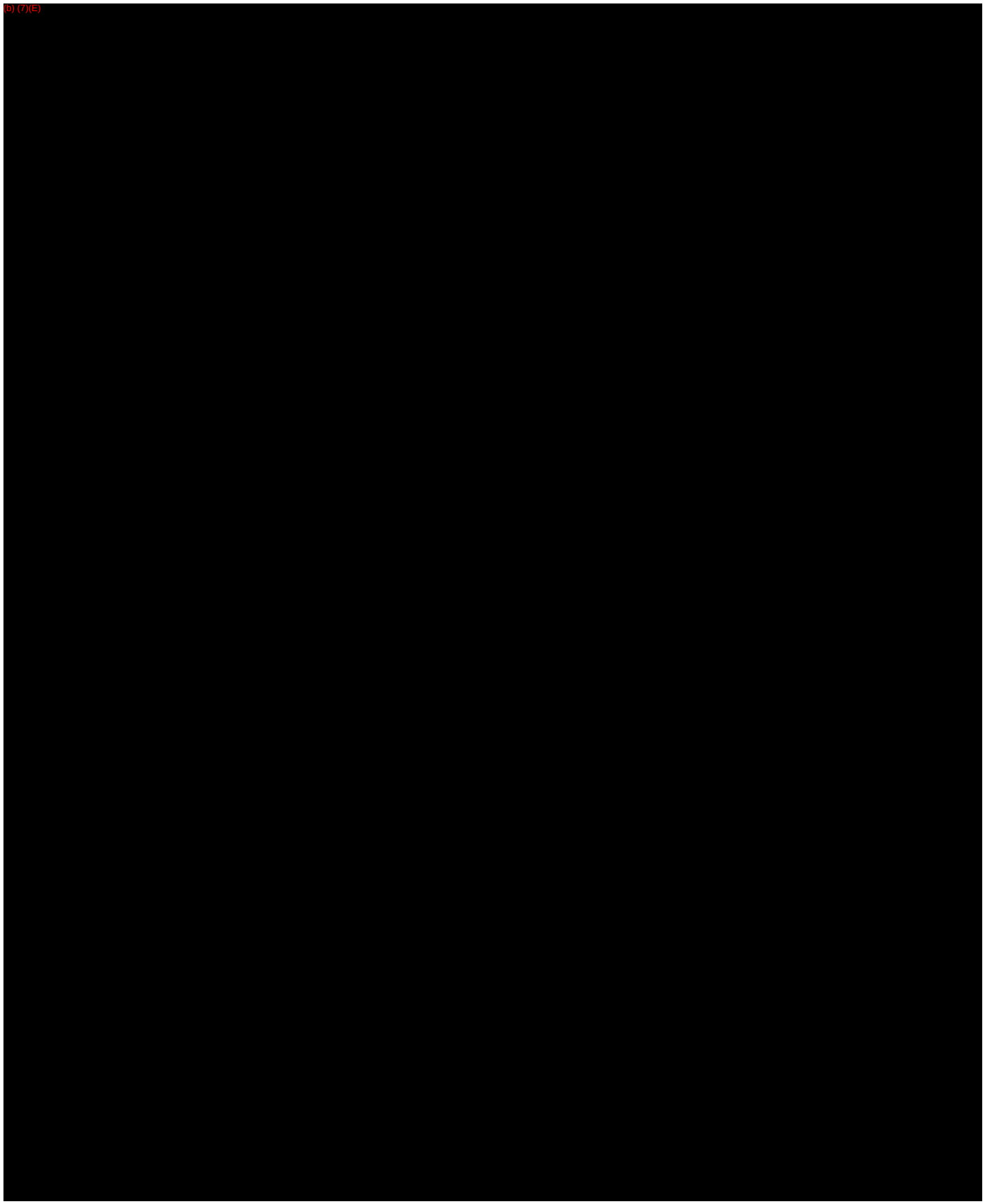

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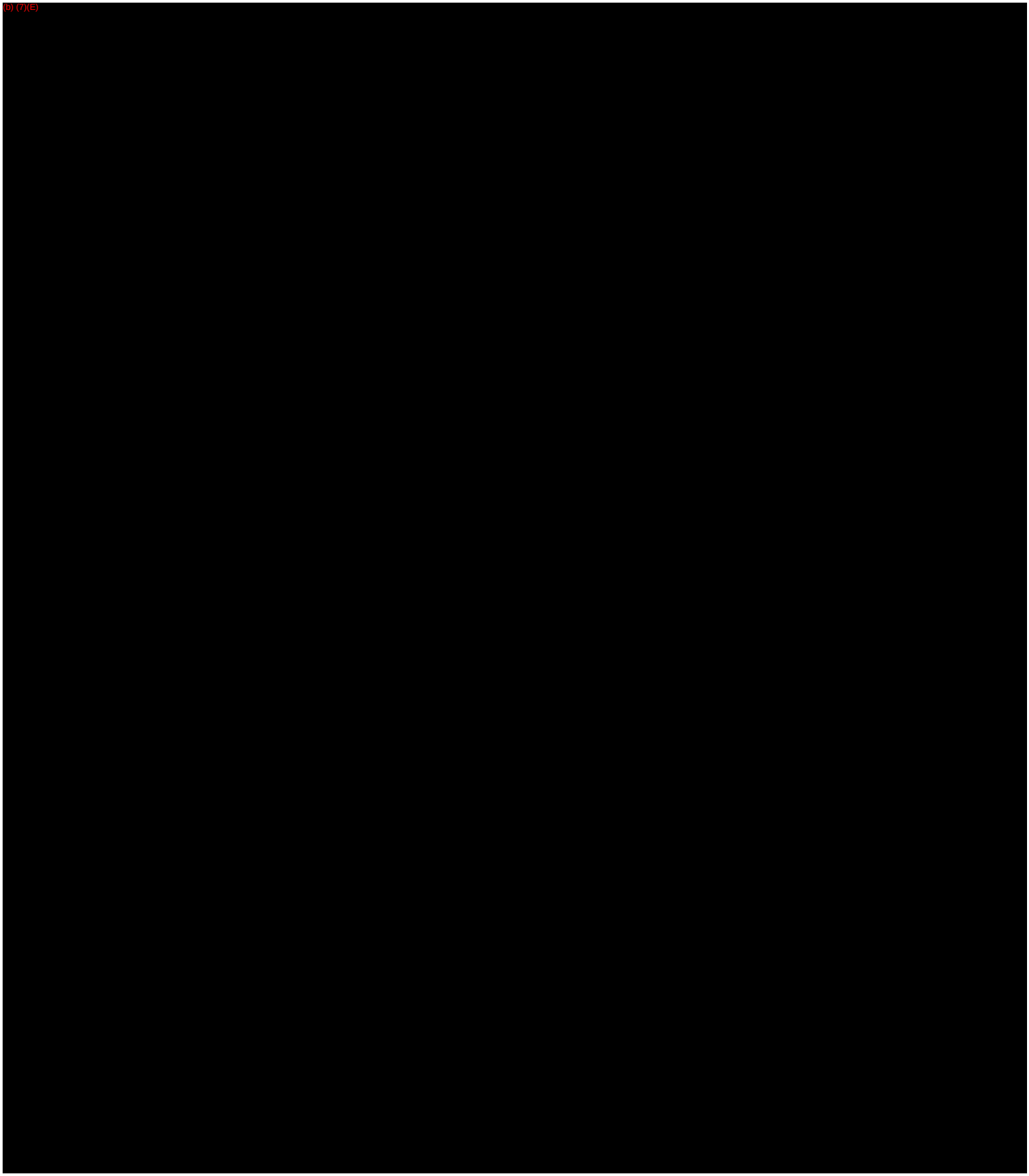

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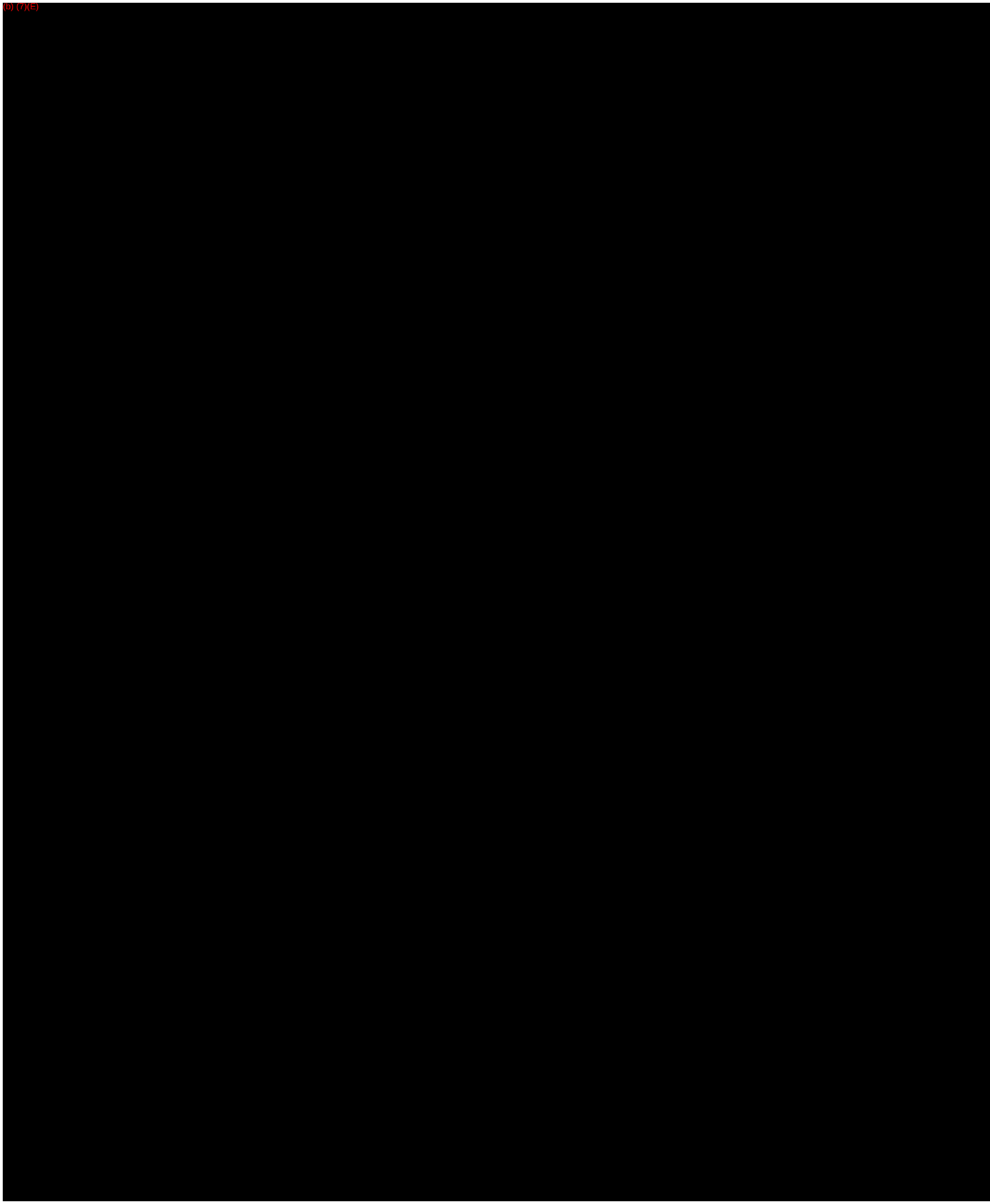
References

Immunalysis Corporation Package Insert, Revision: A.2, KI-350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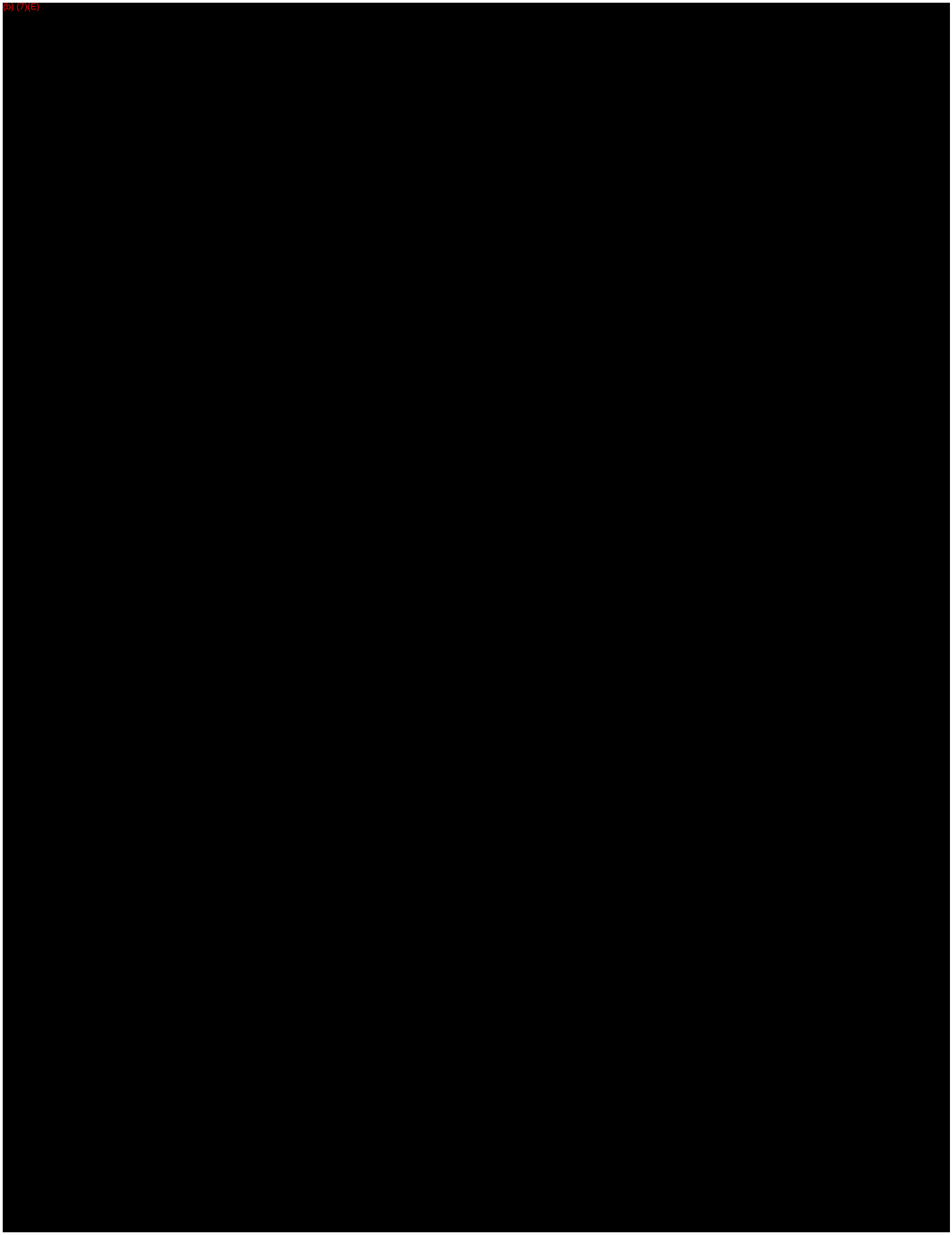

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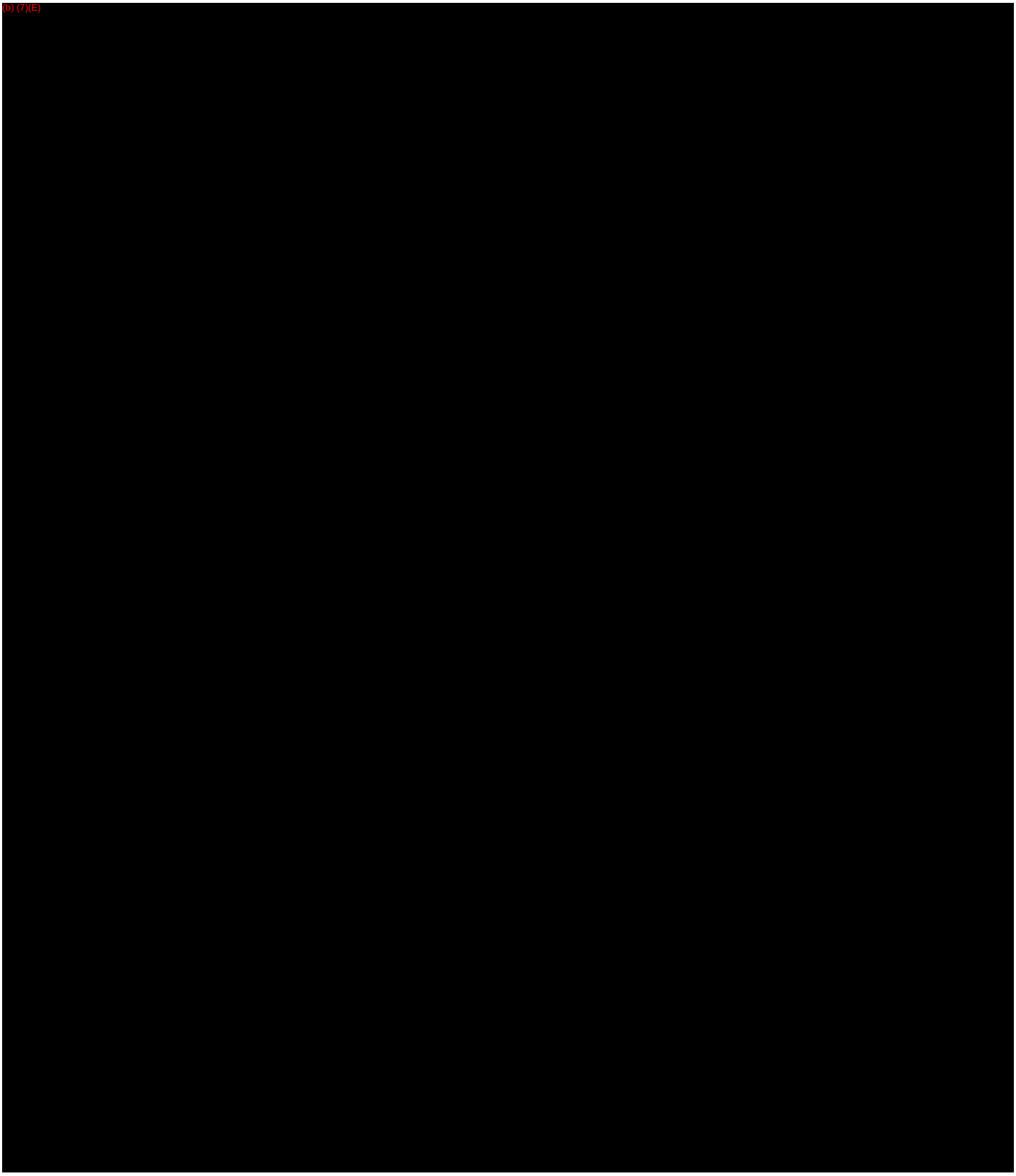

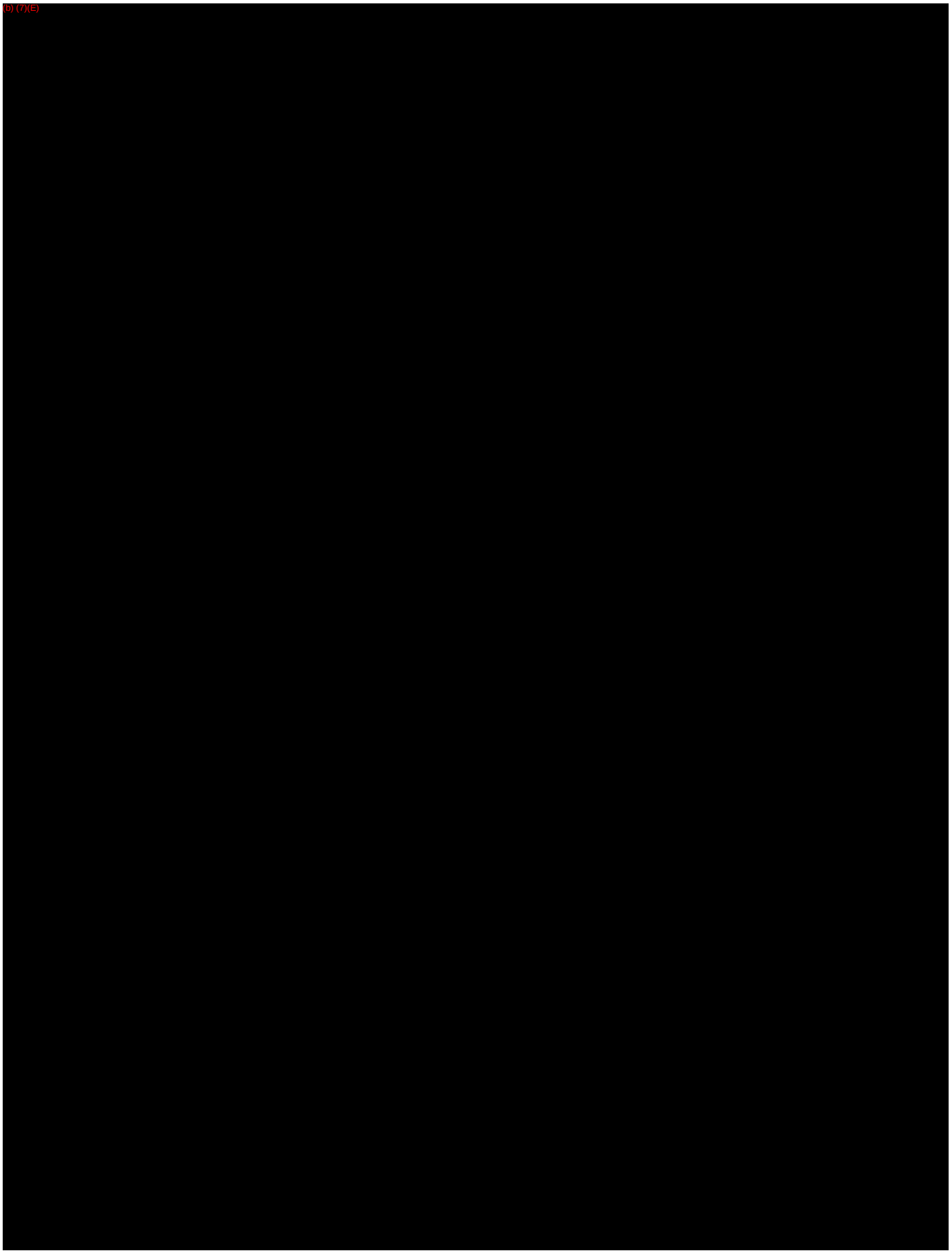
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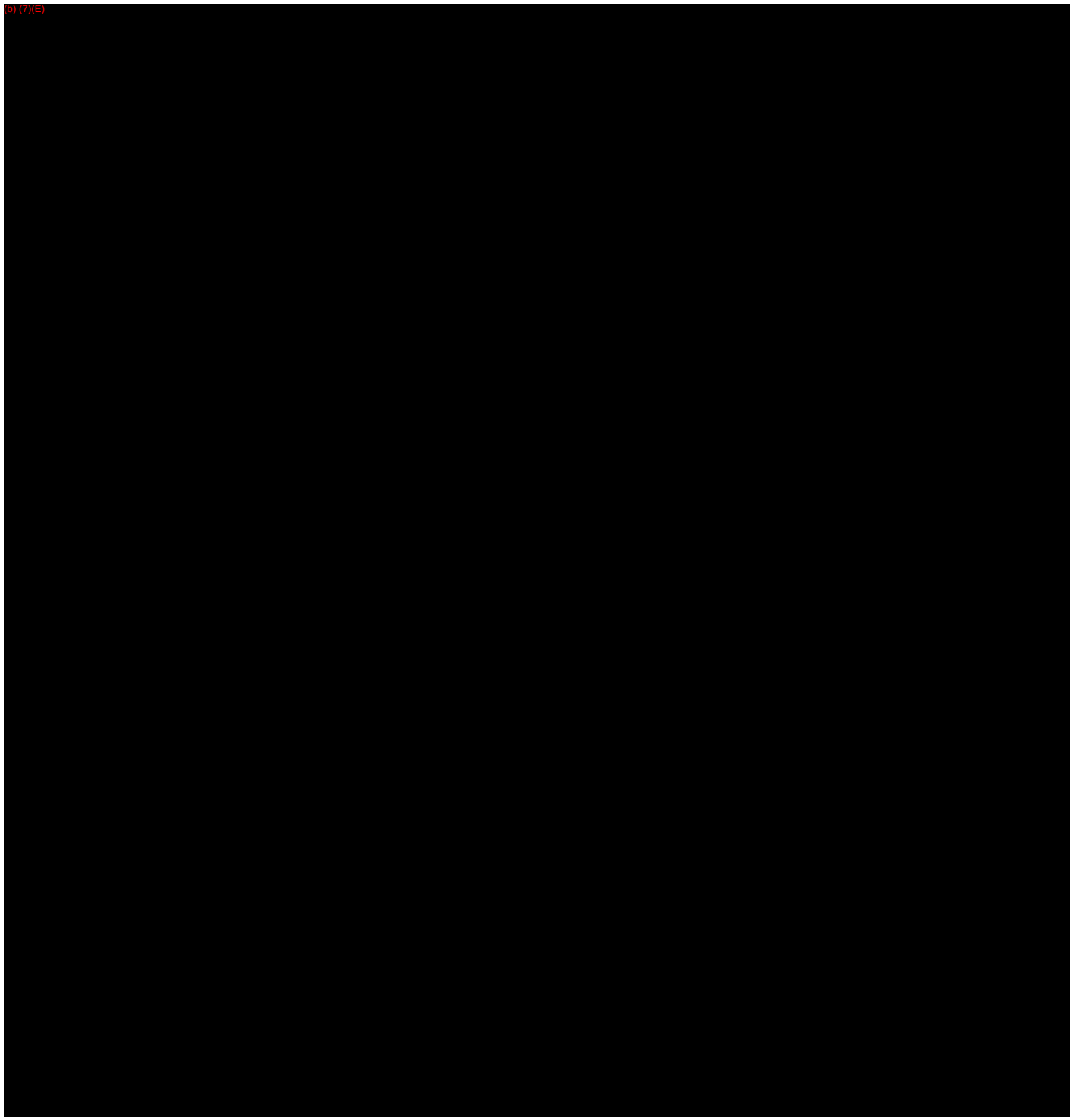
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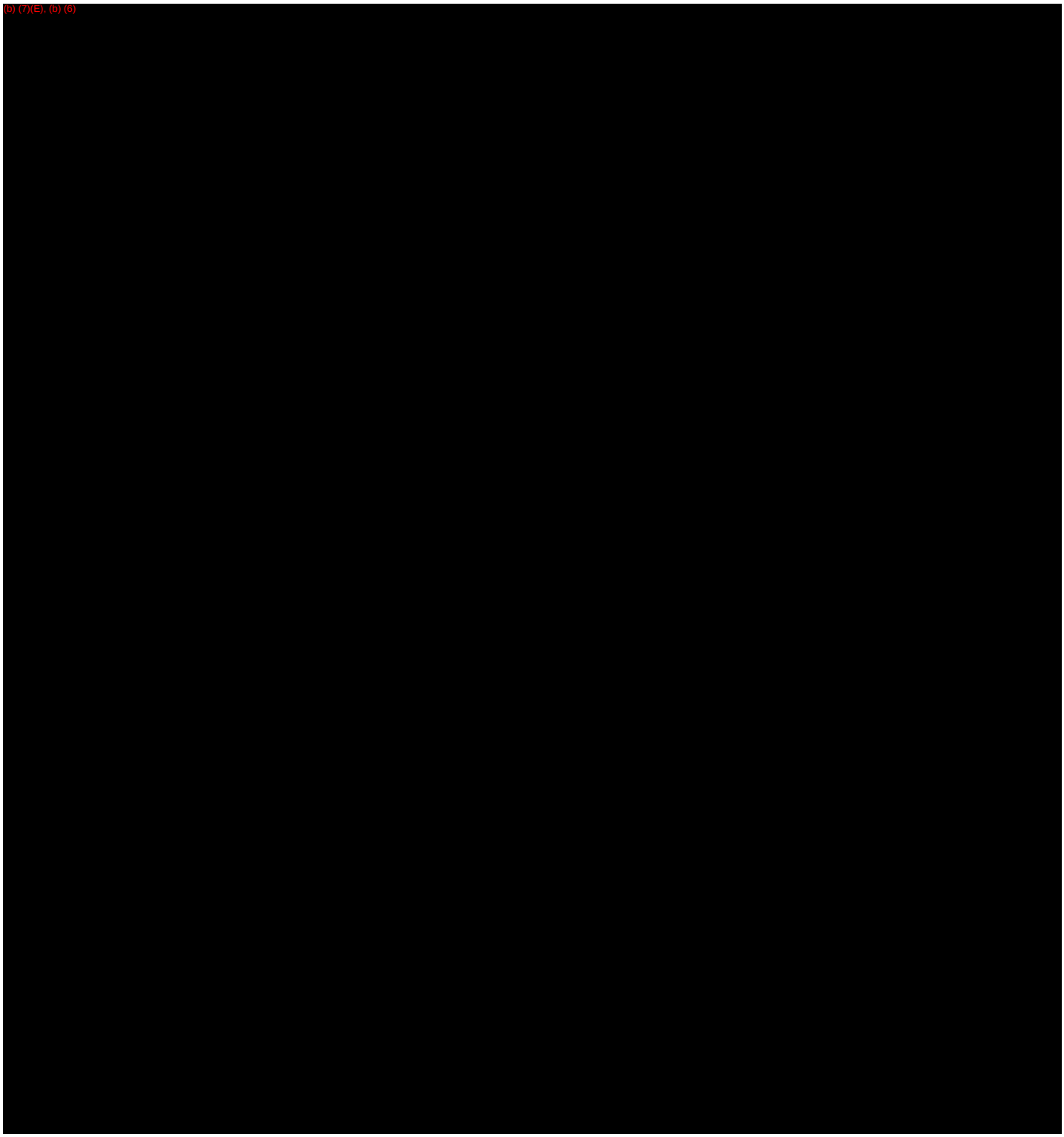
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OFFICE OF FORENSIC TOXICOLOGY SERVICES

CHAPTER EIGHT

SOLUTION AND BUFFER PREPARATION AND CALCULATIONS

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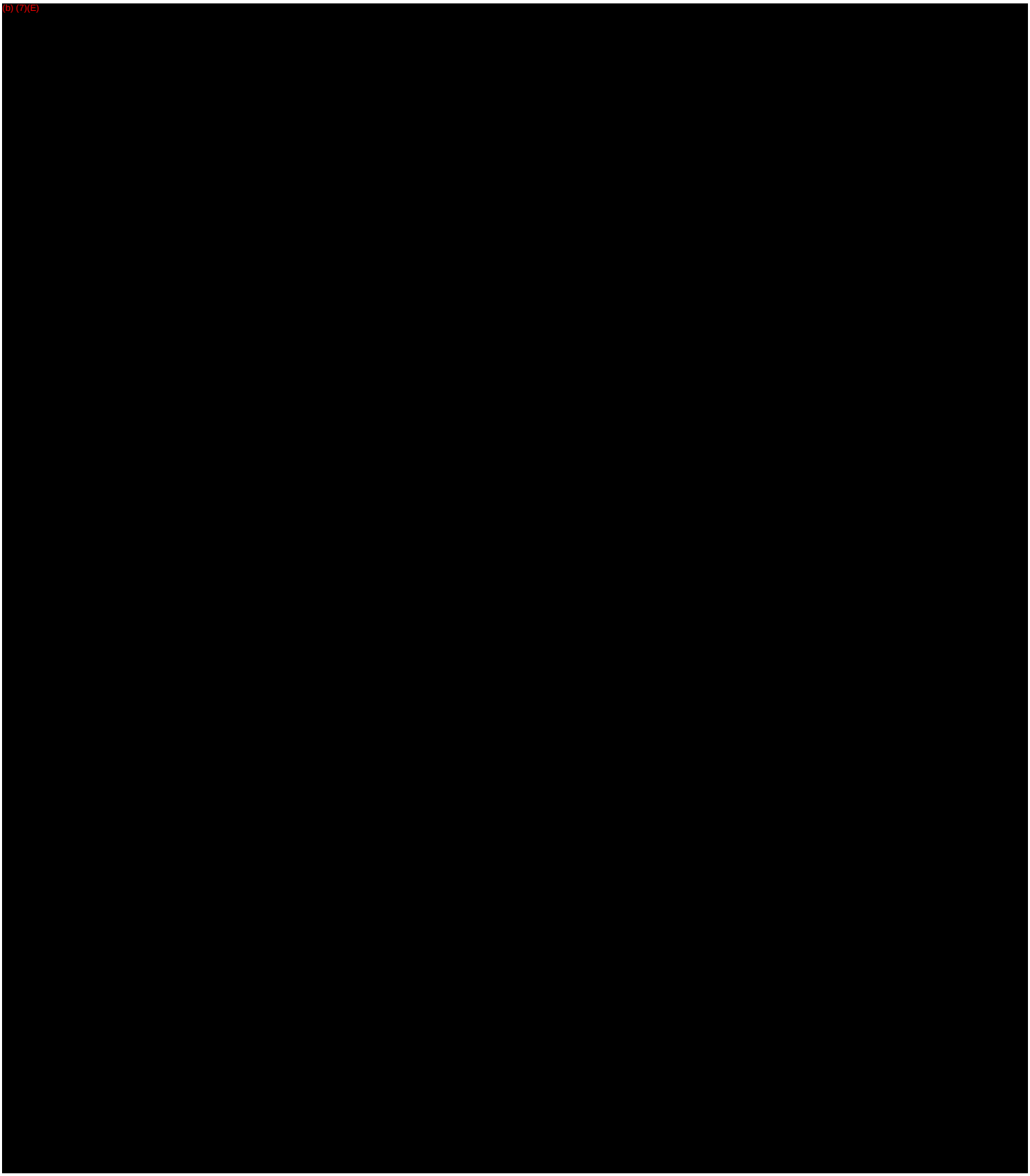


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