

- RCRA, 42 U.S.C. § 6928(a). Maryland has not sought authorization to implement the federal universal waste regulations applicable to spent lamps. Therefore, in Maryland, waste lamps are regulated as hazardous waste, with the characteristic of toxicity for mercury (D009).
4. On July 20, 2022, EPA sent a letter to the State of Maryland, through the Maryland Department of the Environment (“MDE”), giving prior notice of this enforcement action in accordance with Section 3008(a)(2) of RCRA, 42 U.S.C. § 6928(a)(2).
 5. At its facility, located at 8000 Virginia Manor Road, Suite 170, Beltsville, Maryland (“Facility”), Respondent **owns and operates** a diagnostic reference lab that prepares biopsy slides from human tissue. On July 9, 2008, Respondent submitted a notification to MDE that Respondent was a small quantity generator (“SQG”) of hazardous waste at the Facility. MDE had assigned RCRA ID No. MDR000519806 to the Facility. Respondent does not have a permit for the treatment, storage or disposal of hazardous waste at the Facility.
 6. Complainant alleges that, at all times relevant to the allegations described in this Agreement, Respondent was and continues to be a corporation organized under the laws of the State of Delaware and is therefore a “person,” as defined in Section 1004(15) of RCRA, 42 U.S.C. § 6903(15), and COMAR 26.13.01.03B(61). Respondent was, at all times relevant to the allegations in this Agreement, the “operator” and the “owner” of a “facility,” as described in Paragraph 5, above, as these terms “facility”, “owner” and “operator” are defined in COMAR 26.13.01.03.B(23), (58) and (59), respectively.
 7. At all times relevant to the allegations described in this Agreement, Respondent was a “generator” of, and has engaged in the “storage” in “containers” at the Facility of materials described below that are “solid wastes” and “hazardous wastes,” as these terms are defined in 40 C.F.R. § 260.10, as incorporated by reference in COMAR 26.13.01.03B(29), (76), (9), (73), and (31), respectively.
 8. On March 9, 2020, EPA representatives conducted a Compliance Evaluation Inspection (“Inspection” or “CEI”) at the Facility to determine compliance with the applicable hazardous waste regulations. On February 24, 2022, a Request for Information letter (“RIL”) was electronically mailed to Respondent.
 9. Based on the observations during the Inspection and a review of information obtained from the Respondent’s response to the EPA RIL, Complainant alleges and finds that Respondent failed to comply with specific requirements of Subtitle C of RCRA, 42 U.S.C. §§ 6921 et seq., its implementing regulations at 40 C.F.R. Parts 262, 264, 265, and the federally-authorized Maryland hazardous waste management program regulations codified at COMAR Title 26, Subtitle 13 et seq.
 10. Complainant has identified the following violation at the Facility: Respondent violated 42 U.S.C. § 6925(a) and (e) and COMAR 26.13.07.01A by operating a hazardous waste storage facility without a permit or valid exemption to the permitting requirement as required by COMAR § 26.13.03.05E(1). Respondent failed to meet the following conditions of the generator permit exemption:

- a. On at least March 9, 2020, the 55 gallon container in the Facility's storage area was labeled hazardous waste flammable liquids Xylene and Ethanol with waste codes F003 and D001. The labeled was not marked with the date upon which accumulation first began. Respondent failed to mark the container of hazardous waste with the date upon which accumulation first began, in violation of COMAR 26.13.03.05E(1)(e).
 - b. On at least March 9, 2020, the Contingency Plan maintained by the Respondent at the Facility did not describe arrangements with local authorities nor did it list the emergency equipment and the locations of such emergency equipment at the Facility, as required by COMAR 26.13.03.05E(1) which incorporates by reference COMAR 26.13.05.04C(3) and (5).
 - c. On at least March 9, 2020, personnel training documents reviewed during the CEI did not provide a program of classroom instruction, online training (e.g., computer-based or electronic), or on-the-job training that teaches Facility personnel how to perform their duties in a way that ensures compliance with as required in COMAR 26.13.05.02G.
11. On at least March 9, 2020, EPA inspectors found during the CEI that several months in 2019 (August and November) where the Facility had three waste pick-ups by Safety Kleen that exceeded 1000 kg. A generator who generates greater than or equal to 1,000 kilograms (2200 lbs) of non-acute hazardous waste in a calendar month is a Large Quantity Generator. A generator who is a large quantity generator for at least one month of an odd-numbered year (reporting year) who ships any hazardous waste off-site to a treatment, storage or disposal facility within the United States must complete and submit EPA Form 8700-13 A/B to the Regional Administrator by March 1 of the following even-numbered year and must cover generator activities during the previous year. The Respondent failed to submit a 2019 biennial report to EPA by March 1, 2020 as required in COMAR 26.13.03.06B.
 12. Complainant and Respondent agree that settlement of this matter for a total penalty of **SIX THOUSAND TWO HUNDRED AND FIFTY DOLLARS (\$6,250)** is in the public interest. In calculating this amount, Complainant considered the statutory factors set forth in Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3), and with specific reference to EPA's October 1990 RCRA Civil Penalty Policy, as revised in June 2003 ("RCRA Penalty Policy"), and the 2021 RCRA Expedited Settlement Agreement Pilot.
 13. Respondent agrees that, within 30 days of the effective date of this Agreement, Respondent shall make a payment of **SIX THOUSAND TWO HUNDRED AND FIFTY DOLLARS (\$6,250)** by one of four methods: 1) electronic funds transfer ("EFT"), 2) Automated Clearinghouse, 3) Pay.gov, or 4) a cashier's check or certified check made out to "**United States Treasury**" with the case name, address and docket number of this Agreement (RCRA-03-2022-0118), for the amount specified above:
 - a. Payment of the penalty amount by EFT:

Federal Reserve Bank of New York
ABA 021030004
Account 68010727
SWIFT address FRNYUS33
33 Liberty Street
New York, NY 10045
Beneficiary: Environmental Protection Agency

b. Payment of the penalty amount by Automated Clearinghouse (“ACH”):

U.S. Treasury REX/Cashlink ACH Receiver

ABA: 051036706
Account Number: 310006, Environmental Protection Agency

CTX Format Transaction Code 22- Checking

Physical Location of the U.S. Treasury Facility
5700 Rivertech Court
Riverdale, MD 20737

Remittance Express (REX): 1-866-234-5681

c. Payments made through Pay.gov:

Payers can use their credit or debit cards (Visa, MasterCard, American Express & Discover) as well as checking account information to make payments. Follow these steps to make a payment:

- (1) You **DO NOT** need a username and password or account.
- (2) Enter **SFO 1.1** in the form search box on the top left side of the screen.
- (3) Open the form and follow the on-screen instructions.
- (4) Select your method of payment from the “Type of Payment” drop down menu.
- (5) Based on your selection, the corresponding line will open and no longer be shaded grey.
- (6) Enter the docket number of this Agreement into the field.

d. Payment of the penalty amount by regular U.S. Postal Service shall be sent via **certified mail** to:

U.S. Environmental Protection Agency
P.O. Box - Cincinnati Finance Center Box 979077
St. Louis, MO 63197-9000

e. Payment of the penalty amount by overnight mail (FedEx or other non-U.S. Postal Service express mail) shall be sent to:

U.S. Environmental Protection Agency
Government Lock Box - Cincinnati Finance Center Box 979077
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63101

- f. A list of the payment methods is also provided at this website <https://www.epa.gov/financial/makepayment>.
14. Within 24 hours of payment, Respondent shall also send proof of payment (a copy of the check, confirmation of credit card or debit card payment, confirmation of wire or automated clearinghouse transfer), by electronic mail to:

Stephen Forostiak, Environmental Scientist (3ED22)
U.S. EPA, Region III
forostiak.stephen@epa.gov

and

Regional Hearing Clerk (3RC00)
U.S. EPA, Region III
R3_Hearing_Clerk@epa.gov

15. In signing this Agreement, Respondent: admits the jurisdictional allegations in this Agreement; neither admits nor denies the specific factual allegations in this Agreement, except as provided in the jurisdictional admission above; agrees not to contest EPA's jurisdiction with respect to the execution of this Agreement, the issuance of the attached Final Order, or the enforcement the Agreement; expressly waives its right to a hearing on any issue of law or fact in this Agreement and any right to appeal the accompanying Final Order; consents to the issuance of the Agreement and agrees to comply with its terms; agrees to bear its own costs and attorney's fees; and agrees not to deduct for federal tax purposes the civil penalty assessed in this Consent Agreement and Final Order.
16. By its signature below, Respondent certifies, subject to civil and criminal penalties for making a false submission to the United States Government, that (1) the alleged violations have been corrected, and (2) any documentation or information provided to EPA was true and accurate.
17. This Agreement and the attached Final Order constitute a settlement by EPA of its claims for civil penalties for the violations alleged in this Agreement.
18. EPA reserves the right to commence action against any person, including Respondent, in response to any condition which EPA determines may present an imminent and substantial endangerment to the public health, public welfare, or the environment. In addition, this settlement is subject to all limitations on the scope of resolution and to the reservation of rights set forth in Sections 22.18(c) and 22.31(a) of the Consolidated Rules of Practice.

Further, EPA reserves any rights and remedies available to it under the RCRA, the RCRA regulations promulgated, and any other federal laws or regulations for which EPA has jurisdiction, to enforce the provisions of this Agreement, following its filing with the Regional Hearing Clerk.

19. Late payment of the agreed upon penalty may subject Respondent to interest, administrative costs and late payment penalties in accordance with 40 C.F.R. § 13.11.
20. This Agreement is effective upon filing, in accordance with 40 C.F.R. § 22.31(b).
21. The undersigned representative certifies that she/he is fully authorized to execute this Agreement and to legally bind Theranostix, Inc.
22. As permitted under 40 CFR § 22.6, the Regional Hearing Clerk will serve copies of this Agreement and Final Order by e-mail to the parties at the following valid e-mail addresses: forostiak.stephen@epa.gov (for Complainant), and bruce.bell@4dx.com (for Respondent).

For Respondent:

Theranostix, Inc.

Date: 12-28-22

By: 
Bruce Bell
Chief Operating Officer

For Complainant: U.S. Environmental Protection Agency, Region III

After reviewing the Agreement and other pertinent matters, I, the undersigned Director of the Enforcement and Compliance Assurance Division of the United States Environmental Protection Agency, Region III, agree to the terms and conditions of this Agreement and recommend that the Regional Administrator, or his/her designee, the Regional Judicial Officer, issue the attached Final Order.

Date: _____

By: _____

[Digital Signature and Date]

Karen Melvin, Director

Enforcement & Compliance Assurance Division

**BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
Philadelphia, Pennsylvania 19103-2029**

IN THE MATTER OF:

Theranostix, Inc.

Respondent,

**Theranostix, Inc.
8000 Virginia Manor Road – Suite 170
Beltsville, MD 20705**

Facility

DOCKET NO.: RCRA-03-2023-0008

**EXPEDITED SETTLEMENT
AGREEMENT AND FINAL ORDER**

**Proceeding under Section
3008(a) and (g) of the Resource
Conservation and Recovery Act, as
amended, 42 U.S.C. § 6928(a) and (g)**

FINAL ORDER

Complainant, the Director of the Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency - Region III, and Respondent, Theranostix, Inc., have executed a document entitled “Expedited Settlement Agreement,” which I hereby ratify as a Consent Agreement in accordance with the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits* (“Consolidated Rules of Practice”), 40 C.F.R. Part 22, (with specific reference to Sections 22.13(b) and 22.18(b)(2) and (3)). The terms of the foregoing Expedited Settlement Agreement are accepted by the undersigned and incorporated herein as if set forth at length.

Based upon the representations of the parties in the attached Expedited Settlement Agreement, the penalty agreed to therein took into account the statutory factors set forth in Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3), and with specific reference to EPA’s October 1990 RCRA Civil Penalty Policy, as revised in June 2003 (“RCRA Penalty Policy”), and the 2021 RCRA Expedited Settlement Agreement Pilot.

NOW, THEREFORE, PURSUANT TO 3008(g) of the Resource Conservation and Recovery Act (“RCRA”), as amended, 42 U.S.C. Section 6991e, and Section 22.18(b)(3) of the Consolidated Rules of Practice, **IT IS HEREBY ORDERED** that Respondent pay a civil penalty in the amount of **SIX THOUSAND TWO HUNDRED AND FIFTYDOLLARS (\$6,250)**, in accordance with the payment provisions set forth in the Expedited Settlement Agreement and comply with the terms and conditions of the Consent Agreement.

This Final Order constitutes the final Agency action in this proceeding. This Final Order shall not in any case affect the right of the Agency or the United States to pursue appropriate injunctive or other equitable relief, or criminal sanctions for any violations of the law. This Final Order resolves only those causes of action alleged in the Expedited Settlement Agreement and does

not waive, extinguish or otherwise affect Respondent's obligation to comply with all applicable provisions of Subtitle C of the Resource Conservation and Recovery Act, 42 U.S.C. §§ 6921 et seq., and the regulations promulgated thereunder.

The effective date of the foregoing Expedited Settlement Agreement and this Final Order is the date on which this Final Order is filed with the Regional Hearing Clerk.

Date: _____

By: _____

Joseph Lisa
Regional Judicial and Presiding Officer
U.S. EPA Region III

**BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
Philadelphia, Pennsylvania 19103**

IN THE MATTER OF:

Theranostix, Inc.

Respondent,

**Theranostix, Inc.
8000 Virginia Manor Road – Suite 170
Beltsville, MD 20705**

Facility

) **DOCKET NO.: RCRA-03-2023-0008**
)
)
) **EXPEDITED SETTLEMENT**
) **AGREEMENT AND FINAL ORDER**
)
) **Proceeding under Section**
) **3008(a) and (g) of the Resource**
) **Conservation and Recovery Act, as**
) **amended, 42 U.S.C. § 6928(a) and (g)**
)
)
)

CERTIFICATE OF SERVICE

I certify that on _____, the foregoing Consent Agreement and Final Order, was filed with the EPA Region III Regional Hearing Clerk. I further certify that on the date set forth below, I caused to be served a true and correct copy of the foregoing to each of the following persons, in the manner specified below, at the following addresses:

Copies served via email to:

Bruce Bell
Chief Operating Officer
Theranostix, Inc.
bruce.bell@p4dx.com

Stephen Forostiak
Environmental Scientist
U.S. EPA, Region III
forostiak.stephen@epa.gov

[Digital Signature and Date]
Regional Hearing Clerk
U.S. Environmental Protection Agency, Region III