US Environmental Protection Agency – Region 2
Caribbean Environmental Protection Division
Response and Remediation Branch

Resource Conservation and Recovery Act (RCRA)
Compliance Evaluation Inspection

Facility Name:	***Hato Rey Pathology Assoc Inc.***		
EPA ID Number:	PRR000027227		
Date of Inspection:	December 28, 2023		
Generator Status in Record:	SQG		
Generator Status at the time of inspection:	LQG		
RCRA Permitted:	No		
Basis for Inspection:	Core Program		
Corrective Action:	No		
Facility Physical Location: (Municipality, PR, zip code)	300 MANUEL DOMENECH AVE. SAN JUAN, PUERTO RICO, 00918.		
Geographical Coordinates:	18.413712, -66.064357		
Facility Director:	Blanca Prieto		
	bprieto@hrplabs.com		
	Mailing address: Same as facility physical location		
Facility EHS Official:	Mayra Rivera Del Valle	787-765-7320 X-290	
	mrivera@hrplabs.com		
	Mailing address: Same as facility physical location		
Area:	Approximately 0.13 ACRES		
Number Employees:	141		
Personnel participating in inspection:			
Inspector's Name	EPA Region 2-CEPD	Enforcement Officer	vazquez.khrystian@epa.gov
Khrystian M. Vazquez	EPA R2	Environmental Scientist	787-977-5860
Status:	FINAL		
Record Schedule:	1044(c)		
EPA Lead Inspector Signature/Date	X Vazquez, Khrystian Type text here Digitally signed by Vazquez, Khrystian Date: 2024.03.06 08:21:29 -04'00'		
Supervisor Signature/Date	X DAVID CUEVAS-MIRANDA Digitally signed by DAVID CUEVAS-MIRANDA Date: 2024.03.06 08:45:09 -04'00' David N. Cuevas Miranda, Ph.D.		

1 INTRODUCTION

On December 28, 2023, a Resource Conservation and Recovery Act (RCRA) Compliance Evaluation Inspection (Inspection) was conducted at Hato Rey Pathology Associates Inc. (the facility), pursuant to Section 3007 of RCRA. As part of the Inspection, an opening meeting, walkthrough, documents review and closing meeting were conducted to evaluate facility's compliance with the requirements that govern hazardous waste generators, universal waste handlers and used oil generators, as applicable.

The Facility is located at 300 MANUEL DOMENECH AVE. SAN JUAN, PUERTO RICO, 00918. Refer to *Figure 1* for the aerial location and to *Figure 2* for physical view of the facility, **ATTACHMENT I**.

According to EPA records, the facility was inspected on February 1st 2022 as a Core Program during the COVID-19 pandemic time. The inspection was performed virtually as part of the Off-Site Compliance Monitoring.

2 OPENING MEETING

I arrived at the facility around 10:15 hours and met with the Customer Service Representative, Ms. Yadira Muñoz. She immediately proceeded to notify Ms. Myriam Agosto, the Laboratory Assistant Director, of my presence. We met and had our initial meeting accompanied by, Ms. Blanca Prieto, the Director of the facility and Ms. Mayra Rivera Del Valle, the Health, and Safety Official. I identified myself as EPA RCRA enforcement officer and told the facility representative(s) that the purpose of my visit was to conduct a CEI at the facility to evaluate its hazardous waste management practices and compliance. I also point out that during the COVID 19 Pandemic season we performed an Off-Site Compliance Monitoring during the year 2022.

2.1 FACILITY PHYSICAL DESCRIPTION AND OPERATION

Hato Rey Pathology Assoc Inc (HRP) was founded in February 2012. The facility offers the results (diagnostics) of human base samples to its clients, which include medical offices, hospitals, and/or health facilities. They obtain the samples from their suppliers and perform the necessary number of laboratories tests[1]. Every sample is assigned a unique number, the facility personnel perform the necessary sampling procedure, and then they provide the provider with the result(s) and/or diagnostic data. Before disposing of the samples, they keep them in the original container for two weeks.

The facility has a total area of 0.13 acres of space and has around 141 total employees. Shift hours are from Monday through Friday from 0:500 hours to 23:00 hours.

2.2 SOLID AND HAZARDOUS WASTE GENERATION

According to the facility representatives, they are currently generating alcohol, xylene, and formaldehyde as hazardous waste. They informed that the areas where hazardous wastes are handled,

[1] Patología Anatómica – HRP Labs

stored, and/or disposed of, are their 180-day hazardous waste accumulation area and the two (2) Satellites Accumulation Areas (SAAs). The hauler company for their hazardous waste is Clean Harbor and the last disposal was conducted on December 22, 2023. Finally, I asked them about universal waste and used oil generation at the facility. It was informed that none of the wastes mentioned are nowadays currently being generated at the facility.

3 FACILITY WALKTHROUGH

Before starting the facility walkthrough, I requested the representatives to prepare the required SQG regulated documents to be reviewed after the facility walkthrough. The documents requested were the following:

- Hazardous waste manifest with LDR
- Hazardous waste training
- Basic Contingency Plan

Following the request, the facility representatives Ms. Prieto and Ms. Rivera Del Valle accompanied me during the facility walkthrough. During the facility walkthrough the following areas were inspected:

- Histology Laboratory Satellite Accumulation Area (SAA)
- Cytology Laboratory Satellite Accumulation Area (SAA)
- 180-Days Accumulation Area

The observations for each area are described below. Refer to Appendix 1 for pictures taken during the inspection.

3.1 HISTOLOGY LABORATORY (SAA)

The histology laboratory analyses samples of processing tissues[2], inclusion[3], tint[4] and regular tissue cuts[5]. As part of their process, they generate hazardous waste such as: alcohol, xylene, formaldehyde 10% and tissue basket after sampled. The hazardous waste is generated from the following equipment: Bond-III Fully Automated IHC and ISH Staining System, and the Tissue-Tek Prisma® H&E Stain. Here I met Carlos Sori, the Histology supervisor, where he explained how the laboratory operates.

[2] Tissue processing is the technique by which fixed tissues are made suitable for embedding within a supportive medium such as paraffin, and consists of three sequential steps: dehydration, clearing, and infiltration. (https://pubmed.ncbi.nlm.nih.gov/34859398/)
[3] For observation in light microscopy or electron microscopy, the tissue sections examined are the result of technical procedures which require several successive steps: fixation, inclusion, cutting, staining, mounting. The purpose of **inclusion** is to allow fine and regular cuts. The most widely used inclusion medium is paraffin, but other media are used depending on the mode of preservation of the tissues and the techniques used.
[4] The **sections of the paraffin block** are made with a microtome allowing to make section slices fine enough to be observed by microscopy. The thickness of the sections depends on the microscopy technique used.
[5] The **staining** made on slides, accentuate the contrasts to better recognize the different elements of the preparation. (https://www.clinisciences.com/en/buy/cat-tissue-processing-4165.html)

At the laboratory I observed the following:

- Bio hazard waste container with biohazard red bags containing discarded gloves

See Attachment II Pictures 1-4

3.2 CYTOLOGY LABORATORY (SAA)

The cytology laboratory analyses sample of cervico-vaginal gynecology, thyroid, cerebrospinal fluids, and lungs samples. In addition, they analyze bronchial washing liquid samples[6]. As part of their process, they generate alcohol as hazardous waste from cleansing activities. Here, I also met with Mr. Antonio Rodriguez Garcia where he provided the description of their activities and was accompanied by Andres Monet, the Director of Institutional Programs. At the SAA I observed the following:

- One (1) 5-gallon container labeled as hazardous waste and flammable pictogram containing alcohol (1/4 full)
- Two (2) 5-gallons containers labeled as hazardous waste and flammable pictogram containing alcohol (90 % full)
- One (1) 2-gallon empty container labeled as Xylene

All containers were on top a secondary tray container.

See Attachment II Pictures 5-11

Also, in the same laboratory, attached to a BD PrepMate equipment they have:

- One bottle labeled as hazardous waste containing alcohol, no pictogram

Another testing equipment also had a:

- One bottle labeled as hazardous waste containing alcohol, no pictogram

It was recommended that each bottle had an absorbent material for leaks prevention. Facility representative adopted the recommendation immediately.

See Attachment II Pictures 12-19

- Another SAA stores formalin 10% in two different stainless-steel trays. It was unclear if the formalin was a waste or product. Facility staff explained that when formalin is no longer in use it is sent through a riding conveyor to the 180-days HW Storage Area.

[6] Bronchoalveolar lavage (BAL) is a procedure that is sometimes done during a bronchoscopy. It is also called bronchoalveolar washing. BAL is used to collect a sample from the lungs for testing. During the procedure, a saline solution is put through the bronchoscope to wash the airways and capture a fluid sample (https://medlineplus.gov/lab-tests/bronchoscopy-and-bronchoalveolar-lavage-bal/#:~:text=Bronchoalveolar%20lavage%20(BAL)%20is%20a,and%20capture%20a%20fluid%20sample.)

(More information is needed to expand how and when formalin become hazardous waste).

See Attachment II Pictures 20-26

3.3 180-DAYS HAZARDOUS WASTE ACCUMULATION AREA

The 180-Days Hazardous Waste Accumulation Area is outside the premises. In a designated zinc roof cage with two subdivisions. The area is identified with signs that can be read as "DANGER Hazardous Waste Storage Area". The cage has rail gates secured with padlocks.

Inside the first subdivision I observed the following:

- One (1) 5-gallon white **empty** container labeled as hazardous waste with alcohol
- One (1) 15-gallon white container labeled as hazardous waste with flammable and corrosive pictogram with 37% (dated: 12/14/23)
- One (1) 55-gallon white container labeled as hazardous waste, **no pictogram** containing alcohol (dated: 12/15/23) (Flammable pictogram corrected on the spot)
- One (1) 55-gallon white container labeled as hazardous waste with flammable pictogram with alcohol (dated:12/22/23)
- One (1) 3-gallon white **empty** container labeled as hazardous waste

See Attachment II Pictures 27-32

Inside the second subdivision I observed the following:

- One (1) 55-gallon black steel container labeled hazardous waste, **no pictogram** with xylene (dated: 12/15/23) (Flammable pictogram corrected on the spot)
- One (1) 55-gallon black steel container labeled hazardous waste, **no pictogram** with parafina (paraffin) and xylol (dated: 12/15/23)
- Two (2) 5-gallons **empty** pile orange container labeled hazardous waste with parafina (paraffin)
- One (1) 3-gallon **empty** white container labeled hazardous waste with xylene

See Attachment II Pictures 33-37

I noted that three (3) identified containers did not have the correspondent pictograms attached as well as two (2) HW bottles identified at the Cytology Lab (SAA). I explained the facility representatives that they need to make sure they comply with this regulation. I also explained that it is a good practice that pictograms can be seen easily instead of moving the containers around to make sure it complies. The facility representatives immediately proceeded to attach the pictograms to those containers the lacked them.

See Attachment II Pictures 38-39 for reference

4 DOCUMENTS REVIEW

I reviewed the requested documents after the facility walkthrough. Ms. Rivera Del Valle provided the documents and stayed with me to answer any questions.

4.1 HAZARDOUS WASTE MANIFEST

I reviewed the hazardous waste manifest from the period of 2020, 2021, 2022 & 2023. Most of the hazardous waste code description of the manifest were D001 and F003. Nevertheless, I noted, and in numerous occasions, that the facility generated more the 1,000 Kg. or 2,200 lbs. per month. I explained the facility representatives that they should re-evaluate their hazardous waste generation and determine or reconsider the operation of the facility regarding HW generation.

Manifest from 2020

12/29/2020
Tracking # 0151558454 FLE 110G(D001/F003) 275G(D001/F003) 400P(F003)
Total Pounds= 3,608 **(See Attachment II Picture 40)**

11/18/2020
Tracking #014719875/#013486050 FLE800P(D001/F003) 1,200P(D001/F003) 400(F003)
Total Pounds= 2,400 **(See Attachment II Pictures 41-42)**

10/15/20
Tracking # 015158719/#015158718 FLE 110G(D001/F003) 165G(D001/F003) 450P(F003)
Total Pounds= 2,740 **(See Attachment II Pictures 43-44)**

09/14/2020
Tracking # 0151587851 FLE 110G(D001/F003) 220G(D001/F003)
Total Pounds= 2,748 **(See Attachment II Picture 45)**

08/10/2020
Tracking #014727174/#014727173 FLE 960P(D001/F003) 1920P(D001/F003) 500P(F003)
Total Pounds= 3,380 **(See Attachment II Pictures 46-47)**

07/06/2020
Tracking #014172790/# 014172788 FLE 55G(D001/F003) 220G(D001/F003) 400P(F003)
Total Pounds= 2,690 **(See Attachment II Pictures 48-49)**

06/01/2020
Tracking #014172741/#014172740FLE 165G(D001/F003) 110G(D001/F003)
Total Pounds= 2,290
(See Attachment II Pictures 50-51)

Manifest from 2021

12/14/2021
Tracking #05721964 FLE 800P(D001/F003) 800P(D001/F003) 450P(F003)
Total Pounds= 2,050 (Under 2,200 lbs)
(See Attachment II Picture 52)

11/24/2021
Tracking #015721988 FLE 110G(D001/F003) 165G(D001/F003) 15G(D001/F003)
Total Pounds= 2,414
(See Attachment II Picture 53)

11/01/2021
Tracking #057221980 FLE 55G(D001/F003) 165G(D001/F003) 350P(F003)
Total Pounds= 2,172 **(Under 2,200lbs)**
(See Attachment II Picture 54)

10/11/2021
Tracking #016425244 FLE 500P(D001/F003) 990P(D001/F003) 140P(F003) 460P(F003)
Total Pounds= 2,090 (Under 2,200 lbs)
(See Attachment II Picture 55)

09/21/2021
Tracking #016425220 FLE 55G(D001/F003) 165G(D001/F003)
Total Pounds= 1,832 **(Under 2,200lbs)**
(See Attachment II Picture 56)

09/03/2021
Tracking #016425093 FLE 55G(D001/F003) 165G(D001/F003) 450P(F003)
Total Pounds= 2,282
(See Attachment II Picture 57)

08/09/2021
Tracking #016424975 FLE 165G(D001/F003) 165G(D001/F003) 250P(F003)
Total Pounds= 2,998
(See Attachment II Picture 58)

03/04/2021
Tracking #015455582 FLE 110G(D001/F003) 165G(D001/F003) 450P(F003)
Total Pounds= 2,740
(See Attachment II Picture 59)

12/08/2021
Tracking #013822703 FLE 165G(D001/F003) 165G(D001/F003) 350P(F003)
Total Pounds= 3,098 **(See Attachment II Picture 60)**

Manifest from 2022

01/18/2022
Tracking #015722332 FLE 430P(D001/F003) 1,920P(D001/F003) 200P(D001/F003) 660P(F003)
Total Pounds= 3,210
(See Attachment II Picture 61)

02/08/2022
Tracking #017088365 FLE 480P(D001/F003) 1,200P(D001/F003)
Total Pounds= 1,680 **(Under 2,200 lbs)**
(See Attachment II Picture 62)

03/07/2022
Tracking #017088401 FLE 480P(D001/F003) 1,440P(D001/F003) 140P(D001/F003) 480P(F003)
Total Pounds= 2,540
(See Attachment II Picture 63)

03/28/2022
Tracking #017088414 FLE 900P(D001/F003) 1,320P(D001/F003) 450P(F003)
Total Pounds= 2,670
(See Attachment II Picture 64)

04/25/2022
Tracking #015721811 FLE 110G(D001/F003) 165G(D001/F003) 32G(D001/F003) 450P(F003)
Total Pounds= 3,006
(See Attachment II Picture 65)

06/21/2022
Tracking #017087065 FLE 22G(D001/F003) 165G(D001/F003) 32G(D001/F003) 500P(F003)
Total Pounds= 2,323
(See Attachment II Picture 66)

Manifest from 2023

10/10/2023
Tracking #018206256 FLE 700P(D001/F003) 1,840P(D001/F003) 70P(D001/F003) 400P(F003)
Total Pounds= 3,010
(See Attachment II Picture 67)

08/21/2023
Tracking #018206183 FLE 850P(D001/F003) 1,275P(D001/F003) 125P(D001/F003) 425P(F003)
Total Pounds= 2,675

(See Attachment II Pictures 68-69)

07/06/2023
Tracking #018206102 FLE 850P(D001/F003) 1,700P(D001/F003) 425P(F003)
Total Pounds= 2,975
(See Attachment II Picture 70)

06/13/2023
Tracking #018199476 FLE 900P(D001/F003) 1,600P(D001/F003) 125P(D001/F003) 300P(F003)
Total Pounds= 2,925
(See Attachment II Picture 71)

05/16/2023
Tracking #018199420 FLE 400P(D001/F003) 1,260P(D001/F003) 380P(F003)
Total Pounds= 2,040 **(Under 2,200 lbs)**
(See Attachment II Picture 72)

05/01/2023
Tracking #018199387 FLE 940P(D001/F003) 1,410P(D001/F003) 80P(D001/F003) 290P(F003)
Total Pounds= 2,720
(See Attachment II Picture 73)

04/16/2023
Tracking #017847090 FLE 850P(D001/F003) 1,700P(D001/F003) 325P(F003)
Total Pounds= 2,875
(See Attachment II Picture 74)

03/10/2023
Tracking #017848267 FLE 960P(D001/F003) 1,440P(D001/F003) 130P(D001/F003) 380P(F003)
Total Pounds= 2,910
(See Attachment II Picture 75)

02/16/2023
Tracking #017848203 FLE 425P(D001/F003) 1,250P(D001/F003) 70P(D001/F003) 425P(F003)
Total Pounds= 2,170 **(Under 2,200 lbs)**
(See Attachment II Picture 76)

01/31/2023
Tracking #017846867 FLE 900P(D001/F003) 1,350P(D001/F003) 500P(F003)
Total Pounds= 2,750
(See Attachment II Picture 77)

4.2 HAZARDOUS WASTE TRAINING

Ms. Mayra Rivera provided the certificate of "Hazardous Materials Protection and Safety Training Awareness/Update" (Entrenamiento de Proteccion y Seguridad de Materiales

Peligrosos Concientización/Actualización- 8horas) dated: 8/11/2023

See Attachment III

4.3 BASIC CONTINGENCY PLAN

The basic contingency plan complied with the required element of hazardous waste management, spills and contact information in case of an emergency.

5 CLOSING MEETING

After completion of the walkthrough and document review, I met with Ms. Prieto, Ms, Rivera Del Valle and other staff members to conduct a closing meeting. I indicated that the purpose of the closing meeting is to inform the facility about the CEI observations. I communicated the facility the following:

It was observed at the 180-Days HW Accumulation Area that some containers lacked the HW characteristic identification also known as pictograms. I explained the facility representative that they need to re-evaluate protocols and or practices to improve labeling and marking activities.

HW manifest shows facility to be generating more than 1,000 kg or 2,200 lbs. of HW per month. The generation of hazardous waste turns the facility as a LQG.

6 POTENTIAL AREAS OF CONCERN

6.1 GENERATORS

On August 17, 2021, the Facility notified of its hazardous waste activities as small quantity generator. During the inspection, I confirmed Facility's generator status by verifying its disposal events as described in the manifests and/or the quantity of hazardous waste that was being accumulated onsite (i.e. over 1,000 or 6,000 kg). Based on the observations and information gathered during the inspection, the following areas of concern were identified:

6.1.1 General (40 CFR § 262 Subpart A)[7]

§ 262.13 Generator Category Determination

A generator must determine its generator category. A generator's category is based on the amount of hazardous waste generated each month and may change from month to month. This section sets forth procedures to determine whether a generator is a very small quantity generator, a small quantity generator, or a large quantity generator for a particular month.

§ 262.17 Conditions for exemption for a large quantity generator that accumulates hazardous waste.

262.18 EPA identification numbers and re-notification for small quantity generators and large quantity generators.

§ 262.27 Waste minimization certification.

§ 262.41 Biennial report for large quantity generators.

According to our records and as the facility representatives stated during the initial opening meeting the generation of HW is SQG. At the time of inspection Hazardous Waste Manifests revealed that facility HW generation is as LQG. A LQG must comply with the abovementioned regulations.

262.16 (b)(6)(i)(B)-Pictogram

An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic)

The 180-Days HW Accumulation Area had three (3) identified containers and two (2) bottles at the Cytology Lab that lack of HW characteristic also known at pictograms.

7 FOLLOW-UP ACTIONS

Notice of Violation and Request for Information

8 ATTACHMENTS

I. Figure 1- Facility Location Map and Figure -2 Aerial Photograph
II. Photolog with description
III. Copy of training certificate

[7] https://www.ecfr.gov/current/title-40/chapter-I/subchapter-I/part-262