Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0999846	02/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio De Anatomia Patologica	Edif Central Julio A Perez - Sotano, Rio Piedras, PR	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on Cytology Cytospin centrifuge maintenance worksheet records review (from year 2021 to 2022) and interview with the laboratory director on February 8, 2023 at 11:27 am, it was determined that the laboratory failed to follow the established manufacturer's monthly preventive maintenance when 749 out of 749 cytology patient samples were processed and reported from January 1, 2021 to December 31, 2021: and 289 out of 289 cytology patient samples were processed and reported in the year 2022 on 5 out of 12 moths of year 2022. The findings include: 1. On February 8, 2023 at 10:34 am, the laboratory cytology Cytospin centrifuge maintenance worksheet records were reviewed (from year 2021 to 2022), and showed that the laboratory failed to perform the monthly preventive maintenance which included: grease rubber seal of centrifugal chamber, grease rotor and lube motor shaft. 2. The laboratory failed to perform the cytology Cytospin centrifuge monthly preventive maintenance from January 1, 2021 to December 31, 2021, also during the following months of year 2022: June, July, August, October and December. 3. On February 8, 2023 at 11:27 am, the laboratory director confirmed that the laboratory did not perform the manufacturer's cytology Cytospin centrifuge monthly preventive maintenance from January 1. 2021 to December 31, 2022.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: 1. Based on Gemini AS Slide Stainer Maintenance worksheet record review (years 2021 and 2022), and interview with the laboratory director on February 8, 2023, at 10: 30 a.m., it was determined that the laboratory failed to follow, the every six months, the established manufacturer's preventive maintenance during years 2021 and 2022. The findings include: a. On February 8, 2023, at 10:30 a.m., the Gemini AS Slide Stainer Maintenance worksheet record review, showed that the laboratory must performed, every six months the filter replacement. The records showed that for year 2021 the laboratory performed the preventive maintenance only in December 2021. The laboratory did not perform any every six months maintenance during year 2022. b. On February 8, 2023, at 11:30 a.m., in interview with laboratory director she confirmed that the laboratory did not perform the manufacturer's preventive during year 2021 and 2022. c.The laboratory processed and reported 12,179 out of 12,179 surgical samples for histology from July 1,2021 to December 31,2022. 2. Based on microtome's maintenance's worksheet record review (from year 2021), and interview with the laboratory director on February 8, 2023, at 10:52 a.m., it was determined that the laboratory failed to follow the established manufacturer's monthly preventive maintenance when 7270 out of 7976 surgical samples for histology were processed from January 1, 2021, to December 31, 2021. The findings include: a. On February 8, 2023, at 10:52 a.m., the microtome's maintenance's worksheet records were reviewed showing that the laboratory failed to perform the monthly preventive maintenance which included: lubricate microtome components w/oil 405. The laboratory had five microtomes. b.The laboratory failed to perform the monthly preventive maintenance in the following microtomes: 1. serial #01-44836: January 2021, February 2021, May 2021, June 2021, and August 2021 (5 out of 12 monthly preventive maintenance). 2. serial #01-44837: January 2021, February 2021, May 2021, June 2021, July 2021, and November 2021. (6 out of 12 monthly preventive maintenance). 3. serial #01-53227: January 2021, February 2021, May 2021, June 2021, July 2021, and August 2021. (6 out of 12 monthly preventive maintenance). 4. serial #01-51368: January 2021, February 2021, April 2021, May 2021, June 2021, July 2021, August 2021, September 2021, October 2021, November 2021, and December 2021. (11 out of 12 monthly preventive maintenance). 5. serial #01-45112: January 2021, February 2021, April 2021, May 2021, June 2021, July 2021, August 2021, and September 2021. (8 out of 12 monthly preventive maintenance). c. During interview with the laboratory director, on February 8, 2023, at 11:30 a.m., she confirmed that the laboratory did not perform the manufacturer's monthly preventive maintenance from January 1, 2021 to December 31, 2021.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the

reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
1. Based on Cytology area room temperature record review (from year 2021 to 2022) and interview with the laboratory director on February 8, 2023 at 9:48 am, it was determined that the laboratory failed to take and document corrective action when the cytology room temperature was less that the established temperature range. The findings include: a. On February 8, 2023 at 9:49 am, the laboratory cytology room temperature and relative humidity log records were reviewed. The records showed an established temperature range of 15to 25 C. b. On February 8, 2023 at 9:52 am, the laboratory room temperature and relative humidity log records showed that the laboratory documented a room temperature of 12C on the following dates: 1/11/21, 1 /12/21, 1/19/21, 1/20/21, 1/21/21, 1/22/21, 1/25/21, 1/26/21, 1/27/21, 1/28/21, 1/29 /21, 2/1/21, 2/2/21, 2/3/21, 2/4/21, 2/5/21, 2/8/21, 2/9/21, 2/10/21, 2/11/21, 2/12/21 and 2/16/21. c. On February 8, 2023 at 10:05 am, the laboratory director confirmed that the laboratory failed to take and document any corrective action when the cytology room temperature was outside the established range. d. The laboratory processed and reported 365 out of 365 cytology patient samples when the cytology room temperature was outside the established range from 1/11/21 to 2/16/21. 2. Based on Cytology area room temperature and relative humidity log record review (from year 2021 to 2022) and interview with the laboratory director on February 8, 2023 at 10:07 am, it was determined that the laboratory failed to take and document any corrective action when the cytology relative humidity was outside the established range, when 362 out of 362 cytology patient samples were processed and reported on 18 out of 261 days of year 2021 and on 8 out of 261 days of year 2022. The findings include: a. On February 8, 2023 at 9:55 am, the laboratory cytology relative humidity records were reviewed. The records showed that the established relative humidity range was from 60 to 80%. b. On February 8, 2023, at 10:00 am, the relative humidity records showed that the laboratory documented relative humidity between 53 to 59 % on 18 out of 261 days in year 2021 (2/18/21, 2/19/21, 3/3/21, 3/4/21, 3/11/21, 3/18/21, 3/19/21, 4/7/21, 4/8/21, 4/9/21, 4/12/21, 4/15/21, 4/21/21, 4/22/21, 4/23/21, 4/29/21, 5 /17/21, 5/18/21). Also on 8 out of 261 days in year 2022 (1/3/22, 1/4/22, 1/5/22, 3/15 /22, 3/16/22, 3/17/22, 3/18/22 and 3/21/22). c. The laboratory processed and reported 363 out of 362 cytology patients samples during the mentioned dates. d. On February 8, 2023 at 10:07 am, the laboratory director confirmed that the laboratory failed to take and document any corrective action when the cytology relative humidity was outside the established range. 3. Based on pathology laboratory room temperature and relative humidity log record review (years 2021 and 2022) and laboratory director interview on February 8, 2023 at 9:57 am, it was determined that the laboratory failed to take and document corrective actions when the relative humidity was above the established range on 115 out of 261 days of year 2021. The findings include: a. On February 8, 2023 at 9:57 am, the laboratory room temperature and relative humidity log were reviewed. The records showed an established relative humidity range of 60 to 80 %. b. On February 8, 2023 at 10:00 am, the relative humidity log showed that the laboratory documented relative humidity ranges between 85 to 86% from January 1, 2021 to June 30, 2021. c. On February 8, 2023 at 10:08 am, the laboratory director confirmed that the laboratory failed to take and document any corrective action when the relative humidity was above the established range. d. The laboratory processed and reported a total of 3,862 surgical samples for histology from January 1, 2021 to June 30, 2021. 4. Based on the laboratory room temperature and relative humidity log review (years 2021 and 2022) and laboratory director interview on February 8, 2023

	at 12:06 pm, it was determined that the laboratory failed to take and document corrective action when the room temperature was above the established range of 15 to 25 C on ten out of 119 days of year 2022 (July 1, 2022 to December 31, 2022). The findings include: a. On February 8, 2023 at 12:06 pm, the laboratory room temperature and relative humidity log were reviewed. The records showed an established room temperatures range of 15 to 25 C. b. On February 8, 2023 at 12:08 pm, the room temperature records showed that the laboratory documented a room temperature of 26C in July 2022. c. On February 8, 2023 at 2:06 pm, the laboratory director confirmed that the laboratory failed to take and document any corrective action when the room temperature of the laboratory was above the established range.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on the Pathology Frozen sections patient records review (from year 2021 to 2023), and interview with the laboratory director on February 8, 2023 at 2:48 pm, it was determined that the laboratory failed to document the diagnostic result time, total turnaround time (minutes), basic case (yes or no) and case analysis, when two out of 30 total samples of Pathology Frozen samples where processed and reported from January 4, 2021 to January 22, 2021. The findings include: 1. On February 8, 2023 at 2:00 PM, the Pathology Frozen section patient log book records were reviewed (from year 2021 to 2023). The records showed that the following information must be documented:sample collection date, name of the patient and/or record number, pathologist, surgical sample number, organ, receiving time, diagnostic result time, total time (minutes), basic case (yes or no), case analysis (cases that took over 30 minutes), number of blocks and formalin verification. 2. On February 8, 2023 at 2:20 pm, the Pathology Frozen section records showed that the laboratory did not document the following information:diagnostic result time, total turnaround time (minutes), basic case, not the case analysis when two out of 30 total Pathology Frozen samples where processed and reported from January 4, 2021 to January 22, 2021. 3. On February 8, 2023 at 2:48 pm, the laboratory director confirmed that the laboratory did not document the diagnostic results time, total turnaround time (minute), basic case, not the case analysis on those case analysis that took over 30 minutes.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on the Pathology Frozen sections patient records review (from year 2021 to

	2023), and interview with the laboratory director on February 8, 2023 at 2:45 pm, it was determined that the laboratory failed to document the case analysis of those samples that took over the established turnaround time limit of 30 minutes, when one out of 15 Frozen patient samples were processed and reported from February 4, 2022 to February 11, 2022 and one out of five Pathology Frozen patient samples were processed and reported from February 2, 2023 to February 8, 2023. The findings include: 1. On February 8, 2023, at 2:00 pm, the Frozen section patient records were reviewed (from year 2021 to 2023). The records showed that the following information must be documented: sample collection date, name of the patient and / or record number, pathologist, surgical sample number, organ, receiving time, diagnostic result time, total time (minutes), basic case(yes or no), case analysis(cases that took over 30 minutes), number of blocks and formalin verification. 2. On February 8, 2023 at 2:08 pm, the records showed that, on February 7, 2022, the case number AB S22-695 showed a turn around time of 82 minutes. On February 7, 2023, the case number S23-775 record showed a turn around time of 51 minutes. The laboratory did not document the case analysis (1-complex organ or specimen, 2-Difficult diagnosis, 3-Unannounced and the pathologist is outside the laboratory, 4-Pathologist prepare slides, 5-Unannounced consult during second or third shift) of both cases that took more than 30 minutes. 3. On February 8, 2023 at 2:45 pm, the laboratory director confirmed that the laboratory failed to document the case analysis of those samples that took over the established turnaround time limit of 30 minutes on February 7, 2022 and February 7, 2023, and did not take any corrective action.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on quality control records review and interview with the laboratory director on February 8, 2023 at 2:48 pm, it was determined that the laboratory director did not assure that the established quality control program for Cytology and Histopathology areas were followed. Refer to D 5411 (No followed manufacturer's instructions for the Cytology Cytospin centrifuge preventive maintenance). Refer to D 5429 (1) (2) (No followed manufacturer's instructions for Gemini AS Slide Stainer and microtomes preventive maintenance). Refer to D 5781 (1) (2) (3) (4) (No taken nor documented corrective actions when the room temperature and the humidity failed to meet the laboratory's established range. Refer to D 5787 (No documented the required information in frozen section records).