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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 40D0658324 | (X3) Date Survey Completed 10/25/2022 |
| Name of Provider or Supplier Laboratorio De Patologia | Street Address, City, State Escuela De Medicina Rio Piedras, San Juan, 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 |
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| D5415 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on review of histopathology reagents lot records (year 2022) and interview with the laboratory director on October 25, 2022 at 10:15 am, it was determined that the laboratory performed Hematoxilin and Eosin staining without the complete reagents information since January 2022. The findings include: 1. The laboratory performed the Hematoxilin and Eosin staining in patients tissue specimens 9 993-22-A1, A2 and A3) on 08/19/2022. 2. On October 25, 2022 at 10:15, the histopathology reagents lot records showed that the laboratory did not document the required reagent information: lot number, expiration date, date received, date placed in routine used since January 2022. 3. The laboratory director confirm at 10:18 AM that the laboratory fail to document the reagent lot number, expiration date, date received, date placed in routine used.</p> |
| D5417 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> |

This STANDARD is not met as evidenced by:
 Based on observation, review of quality control records of Hematoxilin and Eosin stain (year 2022) and interview with the laboratory testing personal on October 25, 2022 at 10:15 am, it was determined that the laboratory stained smears of patient tissue specimens with the Eosin stain reagent that exceeded the expiration date. The findings include: 1. On October 25, 2022 at 10:15 am, the Eosin stain reagent lot 0034 in used showed exceeded the expiration date on 2021-08-03. 2. The quality control records of Hematoxilin and Eosin stain showed that the laboratory stained the patients specimens smears 993-22-A1, A2 y A3 on 08/19/2022. 3. On 10:18 am, the testing personal confirmed that the Eosin stain reagent lot 0034 in used showed exceeded the expiration date on 2021-08-03.

D5601

HISTOPATHOLOGY
 CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
 Based on review of the immunohistochemical quality control records(year 2022) and interview with the laboratory director on October 25, 2022 at 12:35 AM , it was found that the laboratory did not document the observed reactions of the control slides from 8 /15/2022 to 8/18/2022. The findings include: 1. The laboratory perform immunohistochemical stains. 2. On October 25, 2022 the immunohistochemical quality control records showed that the laboratory did not document the observed (negative nor positive) reactions on the following dates: Patient number : IP-993-2022 stained on 8/18/2022, immunohistochemical's: EBERCISH. Patient number : IP-987-2022 stained on 8/18/2022, immunohistochemical's: HHV-8(1 3B10), CD-38. Patient number : IP-977-2022 stained on 8/15/2022, immunohistochemical's: CD-19, Kappa-Prot-cellM, Lamba-Prot-cellM,CD-138, CD-38. Patient number : IP-956-2022 stained on 8/15/2022, immunohistochemical's: MSH2(G219) OPI, PMS2 (A16-4) OPTI, MSH6 (SP93), MSH6 (SP93) OPTI, MLHI (M1)OPTI. 3. The laboratory director stated on October 25, 2022 at 12:38 AM, that the pathologist did not document the quality control slides observed reactivity.

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 observation, review of quality control records of Hematoxilin and Eosin stain, histopathology reagents lot records, immunohistochemical quality control record and interview with the laboratory director on 10:15 am, sit was determined that the laboratory director failed to maintain the quality control procedures of the

histopathology laboratory. Refer to D 5415 (The laboratory performed Hematoxilin and Eosin staining without the complete reagents information since January 2022). Refer to D 5417 (The laboratory stained smears of patient tissue specimens with the Eosin stain reagent that exceeded the expiration date). Refer to D 5601 (The laboratory did not document the observed reactions of the immunohistochemistry control slides from 8/15/2022 to 8/18/2022).

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment 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 Assessment (QA) records review and laboratory director interview on October 25, 2022 at 10:50 AM, it was determined that laboratory director failed to ensure compliance with QA requirements since September 2021. The findings include: 1. The laboratory establish an every three months evaluation for the following QA activities: sample integrity, historical clinical information, peer review, diagnostic consultation, turn around time and out side consultation. 2. On October 25, 2022 at 10:50 AM, the QA records showed that the laboratory did not evaluate the QA activities since September 2021. Also, the laboratory did not have a records for sample rejection since January 2021. 3. On October 25, 2022 at 11:00 AM, the laboratory director confirmed that the laboratory did not performed the required evaluations and did not have a sample rejection record.