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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 31D1065892 | (X3) Date Survey Completed 06/08/2022 |
| Name of Provider or Supplier Regional Pathologists, Inc | Street Address, City, State 140 Sylvan Avenue, Englewood Cliffs, NJ | |
| 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 |
|---------------------------|---|
| D3043 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7)</p> <p>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Accession Log (AL), Histopathology Slides (HS) and interview with the Clinical Consultant (CC), the laboratory failed to retain HS from 2020. The finding includes: 1. A review of five patient records found on the AL between April 2021 to the date pf survey revealed that one of five patient Quality Control slides was not available at the time of the survey. 2. The CC confirmed on 6/6 /22 at 12:15 pm the HS were not retained.</p> |
| D5469 | <p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be</p> |

established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records and interview with the Clinical Consultant (CC), the laboratory failed to verify that the assayed QC material were within the acceptable ranges before they were put into use for tests performed on the Iris Plus iQ200 elite, Aution May AX-4030 and Biofire FilmArray Torch analyzers from April 2020 to the date of survey. The CC confirmed on 6/6/22 at 1:10 pm that the laboratory did not verify QC material.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Performance Specification (PS) records and interview with the Clinical Consultant (CC), the LD failed to ensure that PS were adequate to perform Chemistry tests performed on the Aution Max AX-4030 analyzers from April 2020 to the date of survey. The findings include: 1. The laboratory did not verify Patient Normal Range. 2. The CC confirmed on 6/6/22 at 11:15 am that not all PS were adequate.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM) and interview with the Clinical Consultant (CC), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with all applicable elements for testing personnel who perform Microbiology and Chemistry testing from April 2020 to the date of survey. The CC confirmed on 6/6/22 at 12:30 pm that a CA procedure was not established with all applicable elements.