Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0882642	03/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Professional Services, Pa	1301 East River Avenue, El Paso, TX	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Review of the CMS 209 Laboratory Personnel Report, policies and procedures, personnel records and interview of facility personnel found that the laboratory failed to have a procedure in place to evaluate the competency of all supervisors, consultants and testing personnel performing high complexity procedures in Histopathology and Cytology in 2022 and 2023. Findings included: 1. Review of the CMS report 209 Laboratory Personnel Report found that the laboratory designated two general supervisors, two technical supervisors, one cytotechnologist general supervisor, one cytotechnologist and three testing personnel for high complexity testing. 2. Review of policies and procedures found that the laboratory had no policy or procedure for assessing the competency of supervisors, consultants or testing personal performing high complexity testing in Histopathology . 3. Review of personnel files found no documentation of competency assessment for the general supervisors, two technical supervisors and three testing personnel performing high complexity testing in histopathology and one provider who also performed Cytology procedures. 3. During interview of the Cytology general supervisor listed on the CMS report 209 conducted on March 19, 2024 at 1:58 PM, she confirmed that the laboratory had not evaluated the competency of all consultants,supervisors,and testing personnel performing high complexity testing in Histopathology and Cytology. A competency assessment evaluation had only been performed for the Cytotechnologist.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1)

	(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. This STANDARD is not met as evidenced by: Based on the review of written laboratory procedures, review of annual test counts and interview of facility personnel, the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established for one of two testing personnel performing Fine Needle Aspirate (FNA) cytology slide interpretations in 2022 until the date of the inspection in 2024. The findings included: 1. Review of the procedure manual found no written policy to ensure that the technical supervisor establishes a maximum workload limit for each testing personnel performing FNA cytology slide interpretations. 2. Review of the annual test counts found the laboratory reported performing 1385 Cytology procedures. 3. During interview of the Cytology General Supervisor conducted March 19, 2024 at 1:58 PM she confirmed the laboratory did not have a procedure to establish workload limits for the pathologists performing fine needle aspirate cytology slide interpretations.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: Based on the review of written laboratory procedures, review of annual test counts and interview of facility personnel, the laboratory failed to establish written policies and procedures to reassess the workload limits at least once every six months for two of two testing personnel performing Fine Needle Aspirate (FNA) cytology slide interpretations in 2022 until the date of the inspection in 2024. The findings included: 1. Review of the procedure manual found no written policy to ensure that testing personnel workload limits were reassessed at least every six months for each testing personnel performing FNA cytology slide interpretations. 2. Review of the annual test counts found the laboratory reported performing 1385 Cytology procedures. 3. During interview of the Cytology General Supervisor conducted March 19, 2024 at 1:58 PM, she confirmed the laboratory did not reassess workload limits for the pathologists performing fine needle aspirate cytology slide interpretations at least once every six months.
D5639	CYTOLOGY CFR(s): 493.1274(d)(2)(i) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the Following: (d)(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition-- (d)(2)(i) The maximum number of 100 slides is examined in no less than an 8-hour workday;

	This STANDARD is not met as evidenced by: Based on the review of written laboratory procedures, review of annual test counts and interview of facility personnel, the laboratory failed to establish written policies and procedures to ensure that one of two testing personnel examined no more than 100 slides in an eight hour workday in 2022 until the date of the inspection in 2024. The findings included: 1. Review of personnel records for testing person two found no workload limits assessed in 2022, 2023 or in 2024. 2. Review of the annual test counts found the laboratory reported performing 1385 Cytology procedures. 3. During interview of the cytology general supervisor conducted March 19, 2024 at 1:58 PM, she confirmed the laboratory did not have a procedure in place to ensure maximum workload limits for the pathologists performing fine needle aspirate cytology slide interpretations were not exceeded.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, testing personnel records and confirmed in interview, the technical supervisor failed to evaluate and document the performance of testing personnel performing high complexity testing in Histopathology and Cytology at least annually for one of two testing personnel in 2022 and 2023. The findings included: 1. Review of the laboratory's policies and procedures indicated that the laboratory had not established a procedure for assessing testing person and consultant competency. Refer to D5209. 2. Review of personnel records from 2022 and 2023 indicated that the technical supervisor had not assessed competency for testing person 2 listed on the CMS-209 provided the day of the survey. 3. During interview of the Cytology General Supervisor conducted on March 19, 2024 at 1:58 PM, she confirmed that a competency assessment for pathologists performing Histopathology and Cytology procedures was not performed annually.
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on the review of written laboratory procedures, review of annual test counts and interview of facility personnel, the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established and reassessed at least once every six months for one of two testing personnel performing

	Fine Needle Aspirate (FNA) cytology slide interpretations in 2022 until the date of the inspection in 2023. Refer to D5633, D5637, and D5639.