

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2007457	(X3) Date Survey Completed 02/06/2024
Name of Provider or Supplier Clinical Pathology Associates Ne Baptist Hospital	Street Address, City, State 8811 Village Drive, San Antonio, 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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's daily histology stain quality records from January 2023 and March 2023, and staff interview, the laboratory failed to have documentation of assessing stain quality on 3 of 3 days. The findings include: 1. A random sampling of histology stain quality records from January 2023 and March 2023 identified 3 of 3 days where the laboratory failed to have documentation of acceptable stain quality. The days were: January 5, 2023 January 23, 2023 March 17, 2023 2. The laboratory was asked to provide documentation of acceptable histology stain quality on the identified days. No documentation was provided. 3. The Clinical Service Manager confirmed the findings after her review of the records on 02/06/2023 at 1424 hours in the office.</p>
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of competency assessments being performed twice within the first year of employment for 1 of 1 personnel requiring them. The findings include: 1. A review of the laboratory's personnel records identified 1 testing personnel who required semiannual competency assessments within the first year of testing during the record review period. They were (as listed on Form CMS 209): Testing personnel number 2 2. Further review of the personnel records revealed: Testing personnel number 2 Hired: 04/2022 One competency assessment performed: 2023 3. The laboratory was asked to provide documentation of 2 competency assessments being performed within the first year of employment for the identified personnel. No documentation was provided. 4. The Clinical Service Manager confirmed the findings during an interview conducted 02/06/2024 at 0915 hours in the office.

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 personnel records and staff interview, the laboratory failed to have documentation of annual competency assessments for 4 of 4 testing personnel requiring them in 2022. The findings include: 1. A review of the laboratory's personnel records identified 3 testing personnel who required annual competency assessments in 2022. They were (as listed on Form CMS 209): Testing personnel number 3 Testing personnel number 4 Testing personnel number 5 Testing personnel number 6 2. Competency assessments for 2022 were not available for 4 of the 4 identified personnel. 3. The laboratory was asked to provide documentation of annual competency assessments being performed in 2022 for each of the 4 identified personnel. No documentation was provided. 4. The Clinical Service Manager confirmed the findings during an interview conducted 02/06/2024 at 0915 hours in the office.