

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1051421	(X3) Date Survey Completed 09/23/2025
Name of Provider or Supplier Hanissian Pediatrics Laboratory	Street Address, City, State 9809 Rowlett Rd, Houston, 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
D0000	The Hanissian Pediatrics Laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of an announced validation survey on 9/23/25 and recertification is recommended. Standard level deficiencies were cited.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) attestation forms, the laboratory's AAB- MLE proficiency testing records, and staff interview, the laboratory failed to have documentation of the laboratory director and testing personnel signatures on four of six attestation statements in 2023, 2024, and 2025. Findings include: 1. A review of the AAB-MLE attestation form revealed the following: "As published in the Federal Register February 28, 1972, Subpart H 493.801(b) (1) "the individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. The undersigned analyst attests that samples were tested in the same manner as patient samples. In addition to the analysts' signature, one of the following must sign once for all analytes reported on this form: Director, Technical Consultant, or Technical Supervisor." 2. A review of the laboratory's AAB-MLE proficiency testing records from 2023, 2024, and 2025 revealed the following 4 events were missing the laboratory director and testing personnel signature on the attestation forms: - AAB-MLE Nonchemistry M3 2023 - AAB-MLE Nonchemistry M1 2024 - AAB-MLE Nonchemistry M3 2024 - AAB-MLE Nonchemistry M2 2025 3. In an interview on 9</p>

/23/25 at 10:35 a.m. in the office, after review of the records, testing person #1 (as indicated on the CMS 209 form) confirmed the above findings.

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of the Horiba M60 Calibration Guide, the laboratory's records, and staff interview, the laboratory failed to have documentation of running quality control materials after calibration procedures for four of five calibrations performed on the Horiba Micros ABX 60 hematology analyzer in 2023, 2024, and 2025. Findings include: 1. A review of the Horiba M60 Calibration Guide (FCD-0412 Rev.1) for the Horiba Micros ABX 60 hematology analyzer revealed that after you accept and validate the calibration run: "Step 15. Run QC as normal." 2. A review of the laboratory's records revealed calibrations were performed on the following dates and the laboratory failed to have documentation of running quality control (QC) materials afterward: - 8/24/23 - 2/20/24 - 8/14/24 - 2/3/25 3. Further review of the laboratory's records revealed the laboratory estimated performing 10,000 hematology tests annually. 4. In an interview on 9/23/25 at 1:10 p.m. in the office, after review of the records, testing person #1 (as indicated on the CMS 209 form) confirmed the above findings.

D6050

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(iv)

(b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's annual competency assessments and staff interview, the technical consultant failed evaluate the direct observation of instrument maintenance and function checks for two of eight testing personnel's competency assessments performed for Complete Blood Count (CBC) testing on the Horiba Micros ABX 60 hematology analyzer in 2025. Findings include: 1. A review of the laboratory's annual competency assessments performed in 2025 revealed the technical consultant failed to evaluate the direct observation of instrument maintenance and function checks for the following 2 testing personnel for CBC testing on the Horiba

Micros ABX 60 hematology analyzer: - Testing person #3 - Testing person #4 2. In an interview on 9/23/25 at 10:40 a.m. in the office, after review of the records, testing person #1 (as indicated on the CMS 209 form) confirmed the above findings.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(v)

(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's annual competency assessments and staff interview, the technical consultant failed to assess test performance through the testing of previous specimens, blind test samples, or external proficiency test samples for two of eight testing personnel's competency assessments performed for Complete Blood Count (CBC) testing on the Horiba Micros ABX 60 hematology analyzer in 2025. Findings include: 1. A review of the laboratory's annual competency assessments performed in 2025 revealed the technical consultant failed to assess test performance through the testing of previous specimens, blind test samples, or external proficiency test samples for the following 2 testing personnel for CBC testing on the Horiba Micros ABX 60 hematology analyzer: - Testing person #3 - Testing person #4 2. In an interview on 9/23/25 at 10:40 a.m. in the office, after review of the records, testing person #1 (as indicated on the CMS 209 form) confirmed the above findings.

D6052

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(vi)

(b)(8)(vi) Assessment of problem-solving skills; and

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's annual competency assessments and staff interview, the technical consultant failed to assess problem solving skills for two of eight testing personnel's competency assessments performed for Complete Blood Count (CBC) testing on the Horiba Micros ABX 60 hematology analyzer in 2025. Findings include: 1. A review of the laboratory's annual competency assessments performed in 2025 revealed the technical consultant failed to assess problem solving skills for the following 2 testing personnel for CBC testing on the Horiba Micros ABX 60 hematology analyzer: - Testing person #3 - Testing person #4 2. In an interview on 9/23/25 at 10:40 a.m. in the office, after review of the records, testing person #1 (as indicated on the CMS 209 form) confirmed the above findings.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's submitted CMS 209 form, personnel files, and staff interview, the laboratory failed to have documentation of the technical consultant performing a competency assessment on three of eight testing personnel in 2024 for

Complete Blood Count (CBC) testing on the Horiba Micros ABX 60 hematology analyzer. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 8 testing personnel performing CBC testing on the Horiba Micros ABX 60 hematology analyzer. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the technical consultant performing a competency assessment in 2024 for the following 3 testing personnel: - Testing Person #6 - Testing Person #7 - Testing Person #8 3. In an interview on 9/23/25 at 12:00 p.m. in the office, after review of the records, testing person #1 (as indicated on the CMS 209 form) confirmed the above findings.

D6066

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(4)(ii)

(b)(6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has-

- (b)(6)(ii)(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens;
- (b)(6)(ii)(B) The skills required for implementing all standard laboratory procedures;
- (b)(6)(ii)(C) The skills required for performing each test method and for proper instrument use;
- (b)(6)(ii)(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;
- (b)(6)(ii)(E) A working knowledge of reagent stability and storage;
- (b)(6)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory;
- (b)(6)(ii)(G) An awareness of the factors that influence test results; and
- (b)(6)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's submitted CMS 209 form, personnel records, and staff interview, the laboratory failed to have documentation of training for six of eight testing personnel prior to performing Complete Blood Count (CBC) testing on the Horiba Micros ABX 60 hematology analyzer in 2024 and 2025. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 8 testing personnel performing CBC testing on the Horiba Micros ABX 60 hematology analyzer. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training for the following 6 testing personnel prior to performing CBC testing: - Testing person #3 hired 6/5/25 - Testing person #4 hired 6/9/25 - Testing person #5 hired 3/24/25 - Testing person #6 hired 12/22/24 - Testing person #7 hired 3/15/24 - Testing person #8 hired 9/3/24 3. In an interview on 9/23/25 at 11:00 a.m. in the office, after review of the records, testing person #1 (as indicated on the CMS 209 form) confirmed the above findings.