

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 65D0970478	(X3) Date Survey Completed 07/22/2025
Name of Provider or Supplier Diagnostic Laboratory Services Inc - Fhp	Street Address, City, State 548 S Marine Corps Dr, Tamuning, GU	
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	Federal Surveyors from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted a recertification survey on 7/16/2025 and 7/22/2025. The following standard level deficiencies were cited.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: A. Based on review of the laboratory's procedures, review of the laboratory's patient mean study records, and interview with technical supervisor #1, the laboratory failed to follow its own procedures and document normal patients used for the patient mean study (2024) changed of innovin for 1 of 1 studies reviewed with the Dade CA 620 coagulation analyzer as evidenced by: 1. In review if the laboratory's procedure G405. 20.03.01 under 5.1 Patient mean study states, "Perform before switching to new lot of PT thromboplastin (innovin) or APTT reagent. Obtain citrated specimens from at least 20 normal patients. These samples can be taken from any of the following patient coming to the laboratory for blood test: patients coming for pre-operation/pre-surgery testing, patient know to be non-coumadin users, patients coming in for immigration testing, non-pregnant women, Patients with no know pathological condition (for annual physical), patient should not be taking any medication, including aspirin, patients should span the adult range." 2. In review of the laboratory's patient mean record effective 12/14/2024 for lot #564632, the laboratory could not identify the 20 patients used for the study. They had no record to determine if the patients met their procedure's criteria. 3. In an interview with technical supervisor #1 on 7-16-2025 at 1119 stated that he didn't know who the normal patients were when they did the study</p>

in December 2024. 38555 B. Based on the review of laboratory procedures, lack of quality control records, and an interview with the technical supervisor (TS), the laboratory failed to establish a manual microscopic urinalysis procedure from July 2023 to July 2025 (24 of 24 months). 1. Review of laboratory QC on July 16, 2025 at 10:00 am, the laboratory was unable to provide a documented QC for manual microscopic urinalysis. 2. The laboratory was requested to provide a manual microscopic urinalysis procedure by July 22, 2025. 3. By interview, on July 22, 2025 at 9:30 am, the TS confirmed the laboratory did not have a procedure for manual microscopic urinalysis. 4. In 2024, 2,297 manual microscopic urinalysis examinations were performed.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions, direct observation of testing personnel #4, and interview with technical supervisor #1, the laboratory failed to follow manufacturer's instructions for reconstituting the Dade Ci-Trol coagulations controls with distilled water as indicated by the manufacturer as evidenced by: 1. In review of the Dade Ci-Trol coagulations control manufacturer's instructions states under preparing reagents, "Add exactly 1 ml of distilled water, gently tilt the vial and allow 15 minutes for reconstitution of the plasma in the close vial." 2. In direct observation of testing personnel #4 at 1405 on 7-16-2025, testing personnel demonstrated that for the coagulation controls they use the Deionized (DI) water from their chemistry instrument to reconstitute the Dade CI-Trol controls. 3. In an interview with technical supervisor #1 at 1407 on 7-16-2025 he confirmed they were using deionized water rather than distilled for reconstitution of the controls.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on observation of the patient draw area, lack of temperature records and interview with the technical supervisor, the laboratory failed to monitor the room temperature of the patient draw area where 6 of 6 boxes of blood collection tubes were stored. Finding Included: 1. Observation of the laboratory patient draw area on July 16, 2025, at 11:30 am revealed the following blood collection tubes were stored

below the countertop in the patient draw area with 4-25 degrees Celsius storage requirements: a. BD Vacutainer Blood Collection tubes - Green top - one box - Lot#4198165. b. BD Vacutainer Blood Collection tubes - Red Top - one box - Lot#4289899. c. BD Vacutainer Blood Collection tubes - Lavender Top - two boxes - Lot#5019856. d. BD Vacutainer Blood Collection tubes - Yellow Top - two boxes. 2. The laboratory was unable to provide room temperature monitoring documentation for the patient draw area. 3. By interview, the TS confirmed on July 16, 2025, at 12:00 pm, that temperatures were not monitored in the patient draw area where collection tubes were stored.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on direct observation, review of manufacturer's instructions, lack of records, and interview with technical supervisor #1, the laboratory failed to indicate the new kit stability expiration date when opened on July 1, 2025, and stored at room temperature for the Becton Dickinson (BD) Affirm kit as evidenced by: 1. In direct observation of the laboratory at 1021 on 7-16-2025 the following kit (that was opened on July 1st, 2025) did not have the new vial stability expiration date indicated and was stored at room temperature: a. BD Lysis lot#4309083 b. BD Affirm VP III L lot #4291399 c. BD Affirm VP III H lot # 4337824 2. In review of the BD Affirm kit manufacturer's instructions states, "Alternatively, store at room temperature (up to 30 degrees C) no more than 3 months." 3. In an interview with technical supervisor #1 at 1022 on 7-16-2025 confirmed that the kit didn't have the new expiration date of 3 months written on the kit or documented in the laboratory's records.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

(d) 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.

This STANDARD is not met as evidenced by:
Based on direct observation, and interview with Technical consultant#1, the laboratory failed to ensure Remel blood sheep agar did not exceed its expiration date with one of one patient cultured as evidenced by: 1. In direct observation of the laboratory on July 22, 2025 at 1015 the following media was expired and used to streak a patient strepococcus throat culture: a. Remel Blood sheep agar expired 7/21 /2025, lot #271260, patient XF51919960 was streaked for culture on the expired blood sheep agar plate. 2. In an interview with technical consultant #1 at 1020 on 7/22/2025, he stated that no, the policy of the lab is not to use expired media.

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(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.

This STANDARD is not met as evidenced by:

Based on the review of laboratory procedures, lack of stain (QC) records, and an interview with the technical supervisor (TS), the laboratory failed to document QC for each microscopic examination in hematology each day of use, for their intended reactivity for six of twelve months (December 2024 to July 2025). Findings included:

1. Review of laboratory procedures revealed that the following tests were performed with the use of Camco Quik Stain II (Buffered Differential Wright-Giemsa Stain): a. RBC Morphology. b. WBC Differential. 2. A review of stain QC records on July 16, 2025, at 2:30 p.m. revealed that the laboratory had not documented positive and negative intended reactivity for the Wright-Giemsa stain since December 31, 2024. 3. By interview, the TS on July 16, 2025, at 4:00 pm confirmed the above findings. Key: RBC = Red Blood Cell. WBC = White Blood Cell.