Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	66D0940277	07/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Diagnostic Lab Services - Saipan	Beach Road, Garapan, MP	

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	A federal surveyor from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted an initial certification survey on 7/25/2025. The following standard level deficiencies were cited:
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory's policy and procedures, and interview with Testing Personnel (TP)-1, according to the Centers for Medicare and Medicaid Services (CMS) Form 209, the laboratory failed to follow its own policy for centrifuge Revolutions Per Minute (RPM) settings for one of one centrifuge. Findings Included: 1. In direct observation on 7/25/25 at 10:55 AM in the laboratory, one Centrifuge (Horizon 24 Drucker, S/N #220509AC773) was seen in use with the following settings: Setting 1 Serum - 3314 RPM, 7 Mins Setting 2 Coag - 3012 RPM, 14 Mins Setting 3 Urine - 1714 RPM, 4 Mins 2. Review of the laboratory's policies and procedures titled 'Diagnostic Laboratory Services, Inc. Urinalysis Technical Procedure UA-SH-001 ver.7' stated the following settings for "Urine Centrifuge Spin Time Chart": "Drucker Horizon 6-flex, Fixed, 1900 RPM, 5 Minutes" The settings were listed for the Drucker Horizon 6-flex and not the Horizon 24 Drucker, for each DLS location, in addition to no settings listed for the DLS Saipan laboratory. 3. In an interview on 7/25/25 at 11:00 AM in the laboratory, TP-1 confirmed the discrepancy between the laboratory's policy and the centrifuge settings.
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: I. Based on direct observation, temperature records, laboratory policy and interview with Testing Personnel (TP) -1, according to the Centers for Medicare and Medicaid Services (CMS) Form 209, the laboratory failed to define the room temperature for two of two years (2023 and 2024). Findings Included: 1. In direct observation on 7/25 /2025 at 10:51 AM in the laboratory, one manual thermometer was seen in use for daily monitoring of laboratory room temperature. 2. Review of the laboratory's room temperature records log sheets for 2023 and 2024 labeled 'Diagnostic Laboratory Services, Inc. Temperature Record Log' showed an acceptable room temperature of 22 to 25 degrees Celsius. 3. Review of the laboratory's policy titled 'Diagnostic Laboratory Services, Inc. Urinalysis Technical Procedure UA-SH-001 ver.7' stated the following range as room temperature: "Storage/Stability: Store at room temperature (15-30 degrees C). Good until expiration date." 4. In an interview on 7/25/2025 at 11: 00AM in the laboratory, TP-1 confirmed the laboratory's acceptable range on the log sheet differed from the room temperatures stated and defined in their policies. II. Based on direct observation, manufacturer's instructions, humidity records, and interview with the Testing Personnel (TP)-1, the laboratory failed to define, monitor and document the humidity in the laboratory where one of one Olympus CX31 microscope was in use. Findings Included: 1. In direct observation on 7/25/2025 at 11: 06AM in the laboratory, one Olympus CX31, Model# CX31RBSFA, SN# 2H10279 was observed in use. 2. Review of the manufacturer's instructions titled 'Olympus Instructions CS31 Biological Microscopy' stated the following humidity requirements: "9. Operating environment - Maximum relative humidity: 80% for temperature up to 31 degrees C, decreasing linearly, through 70% at 34 degrees Celsius, 60% at 37 degrees Celsius, to 50% relative humidity at 40 degrees Celsius." 3. Review of the laboratory's humidity records revealed no humidity ranges defined, monitored or documented in the laboratory where the Olympus CX31 microscope was located. 4. In an interview on 7/25/2025 at 11:07AM in the laboratory, TP-1 confirmed the laboratory had not defined, monitored or documented humidity.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on direct observation, review of the manufacturer's instructions, laboratory's policy, equipment maintenance records, and interview with Testing Personnel (TP)-1, the laboratory failed to perform annual general maintenance servicing to the Olympus

	CX31 microscope for two of two years (2023 and 2024). Findings Included: 1. In direct observation on 7/25/2025 at 11:06AM in the laboratory, one Olympus CX31, Model# CX31RBSFA, SN# 2H10279 was observed in use. 2. Review of the manufacturer's instructions titled 'Olympus Instructions CS31 Biological Microscopy' stated the following maintenance intervals: "Optical components 1) Outer surface, eyepiece, objective, condenser lens, filter, photo eyepiece, 2) Inner part Prism, internal lenses, Maintenance Schedule: Once a year Appearance - Microscope frame, mechanical part, Maintenance Schedule: Once in a year Observation Tube, Maintenance Schedule: Once in a year Mechanical Part - Focusing unit, stage, revolving nosepiece aperture/field iris diaphragm, Maintenance Schedule: Once in two to three years." 3. Review of the laboratory's policy titled 'Diagnostic Laboratory Services, Inc. Microscopy Operation and Maintenance QI-12-EQP-16 ver.2' revealed the following maintenance requirement: "A complete general overhaul (includes full disassembly with cleaning, oiling, reassembly and readjustment) will be performed annually by an appropriately trained specialist." 4. Review of the laboratory's equipment maintenance records revealed no annual general overhaul maintenance performed on the Olympus CX31in 2023 and 2024. 5. In an interview on 7/25/25 at 11:07 AM in the laboratory, TP-1 confirmed that the annual general overhaul maintenance was not performed for the aforementioned years.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory's room temperature records, and interview with the Testing Personnel (TP)-1, according to the Centers for Medicare and Medicaid Services (CMS) Form 209, the laboratory failed to have documentation of performing corrective action when the freezer temperature was outside of the acceptable range for 4 of 18 working days in July 2025 (July 1 - July 25, 2025). Findings Included: 1. In direct observation on 7/25/2025 at 11:06AM in the laboratory, one standard freezer was observed in use set to -30 degrees Celsius to -15 degrees Celsius. 2. Review of the laboratory's temperature record revealed an acceptable temperature range of -30 degrees Celsius to -15 degrees Celsius, and the following dates where the temperature was recorded outside of the range, in July, with no documentation of corrective action: a. 7/1/25 - -14 degrees C b. 7/2/2025 - -13 degrees C c. 7/17/2025 - -14 degrees C d. 7/18/2025 - -14 degrees C 3. In an interview on 7/25/2025 at 11:07AM in the laboratory, TP-1 confirmed the laboratory did not document corrective actions for when temperatures were recorded out of set ranges.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

	(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedures, personnel training and competency records, and interview with Testing Personnel (TP)-1, the technical consultant (TC) failed to evaluate and assure competency for morphological assessment for two of two TPs in 2023. Findings Included: 1. Review of the laboratory's policy procedures titled 'Diagnostic Laboratory Services, Inc. Urinalysis Technical Procedure UA-SH-001 ver.7' stated the following: "2. Morphologic assessment via MTS (Medtraining) is assigned at least annually to technical staff who rotate through the Hematology and Clinical Microscopy department to monitor their consistency in identifying cellular components in urines. Passing rate is 80%. Failures require the completion of the apropritate Training Library module and retaking of quiz. Other recommended methods that will also satisfy this assessment include: 1. Circulation of a pre-graded set of urine sediment slides. 2. Use of former CAP surveys photomicrographs with referee and consensus identifications. Any failure is investigated further by Supervisor and Senior technologist to determine corrective action, i.e., retraining, etc." 2. Review of the laboratory's personnel competency records titled '2023 UA/Microscopy Cell ID Competency' revealed TP-1 and TP-2 failed their 2023 annual competency with the following results, with no documentation of further investigation by the Supervisor and/or Senior Technologist: a. TP-1 - 17/25 (68%) b. TP-2 - 18/25 (72%) 3. In an interview on 7/25/25 at 11:05 AM in the laboratory, TP-1 confirmed the competency failures and lack of further investigation by the TC, in accordance with the laboratory's policy.