

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  65D0959480	<b>(X3) Date Survey Completed</b>  09/27/2021
<b>Name of Provider or Supplier</b>  Northern Region Community Hlth Ctr Lab	<b>Street Address, City, State</b>  520 West Santa Monica Avenue, Dededo, GU	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure Sysmex XP300, review of the Electronic Medical Record (EMR), review of the "carbon patient report form", and interview with technical consultant (TC) #2, the laboratory procedure manual failed to include reportable ranges for complete blood cell (CBC) test results for the test system as established or verified. Findings included: 1. The procedure Sysmex XP300 does not contain validated normal ranges for any of the reported CBC parameters. 2. The "Carbon Patient Report Form" contains normal ranges for the reported CBC parameters that are not reflected in the procedure Sysmex XP300. 3. The normal</p>

ranges for Hgb, RBC, HCT, and MCV as reported in the EMR do not match the normal ranges as shown on the "Carbon Patient Report Form" and are also not reflected accurately in the procedure "Sysmex XP300". 4. Interview with the TC #2 on September 27, 2021 at 3:00 PM confirmed the laboratory failed to include reportable ranges for test results for the test system as established or verified. 5. At the time of the survey on September 27, 2021, the laboratory performed 500 Hematology tests annually.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:  
Based on review of laboratory equipment maintenance records, review of the urine microscopic procedure, and interview with the technical consultant (TC) #2, the laboratory failed to perform and document maintenance for the microscope since 2012 and failed to perform a function check to verify the accuracy of the timer and speed mechanisms on the centrifuge for urine microscopic exams since 2018. Findings: 1. Review of maintenance records showed no documentation for microscope maintenance since 2012. 2. No documentation was available to show the laboratory defined a function check protocol to verify the accuracy of the timer and speed mechanisms on the laboratory centrifuge used for urine microscopy since 2018. 3. Review of the procedure manual revealed "to centrifuge the urine at 2000 rpm for 5 minutes." 4. Approximately 550 urinary microscopic exams were performed annually. 5. Interview with the TC #2 on September 27, 2021 at 3:30 PM confirmed, the laboratory failed to to have a protocol to verify the accuracy of time and speed on the laboratory centrifuge and failed to perform and document microscope maintenance.

**D5801**

**TEST REPORT**  
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:  
Based on random review of patient records (Chart Number 37019/Order#104748), review of the "Sysmex XP300" procedure, review of the Electronic Medical Record (EMR), review of the "carbon patient report form", review of the "Panic Value Log

Form J-2 493.1109 Standard Test Report" form, and interview with technical consultant (TC) #2, the laboratory failed to have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination. Findings included: 1. For Chart Number 37019 /Order#104748 (26-year-old female), the Sysmex XP300 instrument report showed a hemoglobin (Hgb) of 6.0 g/dL (repeat value of 5.9 g/dL) with no indication the value was a "panic result". 2. The Hgb on the "Carbon Patient Report Form" for Chart Number 37019/Order#104748 (26-year-old female) was manually recorded as 6.0 g /dL with no indication the value was a "panic result". 3. The Hgb for Chart Number 37019/Order#104748 (26-year-old female) as reported in the EMR showed as (6.0 L\* g/dL with a reference range of 12-18). a. There was no indication that L\* meant a "panic result". b. The reference range of (12-18) does not correspond to any of the age or gender specific reference ranges in the "Sysmex XP300 procedure section 9.4: Hematology Panic Value Results", which indicated "Male=14-18; Female=12-16; Children=10.7-14.7". c. The "panic result" of 6.0 g/dL does not correspond to the age or gender specific "panic result" ranges for this 26-year- old patient in the "Sysmex XP300 procedure section 9.4: Hematology Panic Value Results", which indicated "Adult Low". 4. The Hgb for Chart Number 37019/Order#104748 (26-year-old female) was recorded on the "Panic Value Log Form J-2 493.1109 Standard Test Report" as "6.4", which does not correspond to the Sysmex XP300 instrument report which showed a Hgb of 6.0 g/dL (repeat value of 5.9 g/dL). 5. "Sysmex XP300 procedure section 9.4 Hematology Panic Value Results" lists "Normal Values" for Hematocrit (%), Hemoglobin(g/dL), and WBC for "children", but does not define the age range that defines "children". 6. Interview with TC #2 on September 27, 2021 at 1: 00 PM confirmed the laboratory failed to have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination. 7. At the time of the survey on September 27, 2021, the laboratory performed 500 Hematology tests annually.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:  
Based on review of 2020 and 2021 personnel competency documentation and interview with the technical consultant (TC) #2, the laboratory director (LD) failed to ensure competency for one of two testing personnel (TP) and one of two technical consultants (TC). Findings: 1. Review of 2020 and to date September 27, 2021 personnel competencies revealed the LD failed to ensure competency for one of two TP of moderate complexity testing and one of two TC. 2. Interview with the TC #2 on

	<p>September 27, 2021 at 3:00PM confirmed the LD failed to ensure competencies for all personnel.</p>
<p><b>D6063</b></p>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Review of personnel records and interview with the technical consultant #2, one of two testing personnel did not have academic qualifications required to perform moderate complexity testing (Refer to D6065).</p>
<p><b>D6065</b></p>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b> CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and</p> <p>This STANDARD is not met as evidenced by: Based on the lack of academic credentials and interview with the technical consultant (TC) #2, the laboratory failed to provide academic credentials to qualify one of two testing personnel (TP) for moderate complexity testing. Findings: 1. The laboratory could not provide foreign equivalency documentation to verify academic credentials for TP #2. 2. Interview with the TC #2 on September 27, 2021 at 3:30 PM confirmed the documents needed to qualify TP #2 were not available for review.</p>