

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2075971	(X3) Date Survey Completed 12/13/2018
Name of Provider or Supplier High Desert Diagnostic Laboratory, Inc	Street Address, City, State 1003 N Division St, Ste 5, Prescott, AZ	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of verification documentation and interview with the facility personnel, the laboratory failed to verify the accuracy of ammonia testing at least twice annually during 2018, which is not included in subpart I of this part. Findings include: 1. The laboratory performs patient testing under the specialty of Chemistry, with an approximate annual test volume of 221,374. 2. It is the practice of the laboratory to participate in Proficiency Testing (PT) for all tests performed by the laboratory. 3. No documentation was presented for review during the survey conducted on December 13, 2018 to indicate the laboratory verified the accuracy of the analyte, ammonia, which is not included in Subpart I of this part. 4. The facility personnel confirmed that the lab did not participate in PT for the analyte, ammonia, during 2018 and did not perform any other verification of accuracy.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on direct inspection of hematology stain reagents and interview with the facility personnel, the laboratory failed to properly label stain reagents used for patient testing in the specialty of Hematology. Findings include: 1. The laboratory performs the Wright stain for manual differentials and to analyze semen morphology. 2. Direct inspection of the 3 coplin jars containing the Wright stain revealed the containers were missing the lot number and expiration date for each reagent component. The jars were labeled as "Diff Kwik Solution 1", "Diff Kwik Solution 2" and "Fixative". 3. The facility personnel confirmed that the coplin jars containing the Wright stain were not labeled with the current lot number and expiration date for each stain component.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 review of the laboratory's maintenance records for the Sysmex CA-600 Coagulation analyzer and interview with the facility personnel, the laboratory failed to perform and document the maintenance during December 2018 as required by the manufacturer. Findings include: 1. The laboratory performs patient testing on the CA-600 Coagulation analyzer in the specialty of Hematology. 2. The CA-600 daily maintenance, as required by the manufacturer, lists 14 tasks including but not limited to, Checking Temperatures and Running "Rinse Probe". 3. No documentation was presented for review during the survey to indicate the laboratory performed the daily maintenance on the following testing dates: 12/06/18, 12/07/18, 12/08/18, 12/11/18, 12/12/18 and 12/13/18. 4. The facility personnel confirmed that the laboratory failed to document the daily maintenance for the CA-600 analyzer on the dates indicated above.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on review of patient test worksheets, patient test reports and interview with the facility personnel, (A) the laboratory failed to include the date of specimen testing in the laboratory's record system for Semen Analysis testing and (B) failed to include the correct collection time on the test report generated from the Laboratory Information System (LIS). Findings include: 1. The laboratory performs Semen Analysis testing, including count and morphology, on patient specimens under the specialty of Hematology. It is the practice of the laboratory to utilize a "Semen Analysis Log Sheet" to record the specimen and test information. The test information is then manually transcribed from the worksheet to the LIS. A2. Review of the test report in

the LIS for patient# 254673 indicated the specimen collection date of 11/29/18 and the final report date as 12/04/18. A3. The Semen Analysis Log Sheet presented for review during the survey for the patient indicated above failed to include the date of specimen testing. A4. The facility personnel stated that the count was performed on 11/29/18 and the morphology was not completed until 12/04/18, but there was no indication of that on the Semen Analysis Log Sheet. B1. The test report generated from the LIS for the patient indicated above listed the specimen collection date and time as 11/29/18 at 14:05, while the Semen Analysis Log Sheet listed the collection date and time as 11/29/18 at 13:05. B2. The facility personnel stated that the collection time was correct on the Log Sheet, however the LIS automatically changes the time to a different time zone.

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 review of patient test reports and interview with the facility personnel, the laboratory failed to have a system in place to ensure the accuracy of test results that are electronically interfaced into the laboratory's information system (LIS). Findings include: 1. The laboratory performs approximately 341,550 patient tests annually under the specialties of Microbiology, Chemistry, Diagnostic Immunology and Hematology. 2. The laboratory performs testing on the following analyzers: Cobas 6000, Beckman DXI, Sysmex XN-1000, Sysmex CA-600 and Tosoh, and the test results are electronically interfaced from the analyzers to the LIS, Hex. 3. No documentation was presented for review during the survey to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are interfaced from the analyzers to the LIS (Hex). 4. The facility personnel confirmed that the laboratory did not have a system in place to verify the accuracy of the patient test results that are sent from the analyzer to the LIS.