

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D1051703	(X3) Date Survey Completed 04/19/2022
Name of Provider or Supplier Desert View Hospital	Street Address, City, State 360 South Lola Lane, Pahrump, NV	
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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on April 19, 2022. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) 2021 Chemistry Core Test Event Three, a review of the API PT 2022 Chemistry</p>

Core Test Event One, and an interview with the Lead Medical Technologist, and the Laboratory director, the laboratory failed to successfully participate in the proficiency testing program for Creatine Kinase and Quantitative human Chorionic Gonadotropin (hCG). (Refer to D2096 and D2107).

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) 2021 Chemistry Core Test Event Three, a review of the API PT 2022 Chemistry Core Test Event One, and an interview with the Lead Medical Technologist, and the Laboratory director, the laboratory failed to achieve successful performance in two consecutive testing events for Creatine Kinase (CK). Findings include: 1. The laboratory failed to submit the 2021 API PT Chemistry Core Test Event Three results to API by the deadline established by the proficiency testing program, resulting in a score of zero for the test event. 2. For the 2022 API PT Chemistry Core Test Event One, the laboratory achieved a score of 60% for the Creatine Kinase test. Specimen numbers CH-01 and CH-02 were each outside the acceptable range established by the proficiency testing program. 3. The findings were confirmed during an interview with the Laboratory Director and the Lead Medical Technologist that was conducted on April 19, 2022 at approximately 10:00 AM. The laboratory performs approximately 260,402 Chemistry tests annually.

D2107

ENDOCRINOLOGY

CFR(s): 493.843(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) 2021 Chemistry Core Test Event Three, a review of the API PT 2022 Chemistry Core Test Event One, and an interview with the Lead Medical Technologist, and the Laboratory director, the laboratory failed to achieve successful performance in two consecutive testing events for Quantitative Human Chorionic Gonadotropin (hCG). Findings include: 1. The laboratory failed to submit the 2021 API PT Chemistry Core Test Event Three results to API by the deadline established by the proficiency testing program, resulting in a score of zero for the test event. 2. For the 2022 API PT Chemistry Core Test Event One, the laboratory achieved a score of 60% for the Quantitative hCG test. Specimen numbers HCG-01 and HCG-04 were each outside the acceptable range established by the proficiency testing program. 3. The findings were confirmed during an interview with the Laboratory Director and the Lead Medical Technologist that was conducted on April 19, 2022 at approximately 10:00 AM. The laboratory performs approximately 260,402 Chemistry tests annually.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) 2020 Hematology/Coagulation Test Event Three, and the API 2021 Hematology/Coagulation Test Event Two records, and an interview with the Laboratory Director and the Lead Medical Technologist, the laboratory failed to document review of the data summary to evaluate results that were not graded due to lack of consensus, or results that were designated as educational challenges for acceptability. Findings include: 1. There was no documentation of a review of the data summary for the API PT 2020 Hematology/Coagulation test event three for the blood cell identification of Specimen BCI-11, which was ungraded due to lack of consensus. 2. There was no documentation of a review for the API PT 2020 Hematology/Coagulation test event three of the ungraded Educational Blood Cell Identification samples ECI-11, ECI-12, ECI-13, ECI-14 and ECI-15. 3. There was no documentation of a review of the data summary for the API PT 2020 Hematology/Coagulation test event for the urine sediment result for specimen number US-06, which was ungraded due to lack of consensus. 4. There was no documentation of a review of the data summary for the API PT 2021 Hematology/Coagulation test event for the blood cell identification of Specimen BCI-07, which was ungraded due to lack of consensus. 5. There was no documentation of a review for the API PT 2021 Hematology/Coagulation test event two of the ungraded Educational Blood Cell Identification samples ECI-06, ECI-07, ECI-08, ECI-09, and ECI-10. 6. The findings were confirmed during an interview conducted with the Laboratory Director and the Lead Medical Technologist on April 19, 2022 at approximately 10:30 AM. The laboratory performs approximately 163,410 hematology tests annually.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on a review of the 2020, 2021, and 2022 American Proficiency Institute (API) Proficiency Testing (PT) records, and an interview with the Laboratory Director and the Lead Medical Technologist, the laboratory failed to ensure that all proficiency testing evaluation and verification activities, including corrective action, were performed and documented. Findings include: 1. A review of the 2020 API Chemistry Core PT event three revealed that the laboratory did not perform and document corrective action for the Troponin I results for specimen numbers CM-13 and CM-15. The Troponin I reported result for specimen CM-13 was 11.04 nanograms/milliliter (ng/ml). The acceptable range for this specimen was 8.39-10.77 ng/ml. The Troponin I reported for specimen CM-15 was 5.31 ng/ml. The acceptable range for CM-15 was 4.06-5.28 ng/ml. 2. A review of the 2020 API Chemistry Core PT event three revealed

that the laboratory did not perform and document corrective action for the Carbon dioxide (CO₂) results for specimen numbers CH-11, CH-13 and CH-14. The CO₂ reported result for specimen CH-11 was 24 millimoles/liter (mmol/L). The acceptable range for this CH-11 was 27-39 mmol/L. The CO₂ reported result for specimen CH-13 was 24 mmol/L. The acceptable range for this CH-13 was 28-40 mmol/L. The CO₂ reported result for specimen CH-14 was 21 mmol/L. The acceptable range for this CH-14 was 23-34 mmol/L. 3. A review of the 2021 API Chemistry Core PT event one revealed that the laboratory did not perform and document corrective action for the Troponin I results for specimen numbers CM-02 and CM-05. The Troponin I reported result for specimen CM-02 was 4.10 ng/ml. The acceptable range for specimen CM-02 was 2.98-3.99 ng/ml. The Troponin I reported for specimen CM-05 was 8.41 ng/ml. The acceptable range for specimen CM-05 was 6.19-8.19 ng/ml. 4. A review of the 2021 API Chemistry Core PT event one revealed that the laboratory did not perform and document corrective action for the calcium result for specimen number CH-04. The calcium reported result for specimen CH-04 was 11.5 milligrams/deciliter (mg/dl). The acceptable range for specimen CH-04 was 11.7-13.8 mg/dl. 5. A review of the 2021 API Chemistry Core PT event one revealed that the laboratory did not perform and document corrective action for the low density lipoprotein (LDL) result for specimen number CH-02. The LDL reported result for specimen CH-02 was 168 mg/dl. The acceptable range for specimen CH-02 was 144-167 mg/dl. 6. A review of the 2021 API Chemistry Core PT event one revealed that the laboratory did not perform and document corrective action for the Sodium result for specimen number CH-04. The sodium reported result for specimen CH-04 was 153 mmol/L. The acceptable range for specimen CH-04 was 160-169 mmol/L. 7. A review of the 2021 API Chemistry Core PT event one revealed that the laboratory did not perform and document corrective action for the Quantitative Human Chorionic Gonadotropin (HCG) result for specimen number HCG-03. The reported result for specimen HCG-03 was 2259.0 milli-international units/milliliter (mIU/ml). The acceptable range for specimen HCG-03 was 2398.5-3681.4 mIU/ml. 8. A review of the 2022 API Chemistry Core PT event one revealed that the laboratory did not perform and document corrective action for the alcohol result for specimen ALC-01. The reported result for specimen ALC-01 was 138 mg/dl. The acceptable range for specimen ALC-01 was 154-258 mg/dl. 9. A review of the 2022 API Chemistry Core PT event one revealed that the laboratory did not perform and document corrective action for the brain natriuretic peptide (BNP) result for specimen CM-04. The reported result for specimen CM-04 was 150 picograms/milliliter (pg/ml). The acceptable range for specimen CM-04 was 113-144 pg/ml. 10. A review of the 2022 API Chemistry Core PT event one revealed that the laboratory did not perform and document corrective action for the creatine kinase (CK) results for specimens CH-01 and CH-02. The reported result for specimen CH-01 was 229 Units/Liter (U/L). The acceptable range for specimen CH-01 was 14-27 U/L. The reported result for specimen CH-02 was 69 U/L. The acceptable range for specimen CH-02 was 246-458 U/L. 11. A review of the 2022 API Chemistry Core PT event one revealed that the laboratory did not perform and document corrective action for the Quantitative Human Chorionic Gonadotropin (HCG) result for specimen numbers HCG-01 and HCG-04. The reported result for specimen HCG-01 was 2397.0 mIU/ml. The acceptable range for specimen HCG-01 was 4560.0-7049.1 mIU/ml. The reported result for specimen HCG-04 was 2573.0 mIU/ml. The acceptable range for specimen HCG-04 was 2646.7-4203.2 mIU/ml. 12. The findings were confirmed during an interview with the Laboratory Director and the Lead Medical Technologist during an interview conducted on April 19, 2022 at approximately 11:00 AM. The laboratory performs approximately 260,402 Chemistry tests annually.

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 the lack of 2020 and 2021 records for the automatic pipette calibrations, the lack of 2020 and 2021 laboratory records for the blood bank refrigerator and freezer alarm checks, and email correspondence with the Lead Medical Technologist on April 21, 2022 and April 26, 2022 the laboratory failed to ensure that the maintenance and function checks were completed in accordance with the laboratory policies and procedures. Findings include: 1. There were no records available of calibration and maintenance of the automatic pipettes since October, 2019. The Lead Medical Technologist confirmed the finding via email received on April 21, 2022. 2. There were no records of blood bank refrigerator and freezer alarm checks. An email received from the Lead Medical Technologist on April 26, 2022 at approximately 4:43 PM stated that the laboratory Standard Operating Procedure (SOP) stated that the refrigerator alarm was to be checked quarterly, and the freezer alarm was to be checked "at regular intervals." The email also stated that the blood bank freezer alarm battery was to be checked monthly. The laboratory performs approximately 186 Microbiology, 260,402 Chemistry, 163,410 Hematology, and 705 Immunohematology tests annually.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on a lack of the 2020 and 2021 laboratory records for the twice per year instrument comparisons for the Dimension EXL 200 and Dimension EXL LM chemistry analyzers, a lack of the laboratory records for the instrument comparisons for the Sysmex XN-450 and Sysmex XN-550 hematology analyzers, a lack of the laboratory records for the instrument comparisons Sysmex CS-2500 and Sysmex CA-660 coagulation analyzers, a review of the director approved policy and procedure entitled, "Instruments Methodology Comparison of Test Results," an interview with the Lead Medical Technologist and the Laboratory Director on April 19, 2022, and email correspondence with the Lead Medical Technologist on April 21, 2022, the laboratory failed to ensure that the twice per year instrument comparisons for the same tests performed on multiple analyzers were performed and accessible for review at the time of the survey. Findings include: 1. There were no records of the twice per year comparison of the instrument results for the Dimension EXL 200 and Dimension EXL LM chemistry analyzers available for 2020 and 2021 for comprehensive metabolic panel, cardiac markers, lipid panel, magnesium and lipase tests performed on both analyzers to verify that each instrument produces consistent results that are

accurate and reliable. 2. There were no records of the twice per year comparison of the instrument results for the Sysmex XN-450 and Sysmex XN-550 hematology analyzers available for 2020 and 2021 for the Complete Blood Counts (CBC) performed on both analyzers to verify that each instrument produces consistent results that are accurate and reliable. 3. There were no records of the twice per year comparison of the instrument results for the Sysmex CS-2500 and Sysmex CA-600 coagulation analyzers available for 2020 and 2021 for the prothrombin time (Protime) and activated Partial Thromboplastin Time (aPTT) performed on both analyzers to verify that each instrument produces consistent results that are accurate and reliable. 4. The director approved policy and procedure entitled, "Instruments Methodology Comparison of Test Results" stated, "It is the policy of Desert View Hospital Laboratory, at the interval of every six months, to compare two production instruments that are expected to produce the same quantitative result." 5. The Laboratory Director and the Lead Medical Technologist stated that the instrument comparison tests had been performed but were not accessible during an interview conducted on April 19, 2022 at approximately 2:00 PM. The Lead Medical Technologist further confirmed the finding that the comparison records were not accessible via email correspondence on April 21, 2022. The laboratory performs approximately 260,402 Chemistry, and 163,410 Hematology tests annually.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on a review of the director approved policy and procedure entitled, "Quality Assurance," a review of the documented quality assessment activities, a review of the records of the automatic pipette calibrations, the lack of 2020 and 2021 records for the comparison of results for the Siemens Dimension chemistry analyzers and the Sysmex hematology and Sysmex coagulation analyzers, the lack of records for the alarm checks for the blood bank refrigerator and blood bank freezer, and an interview with the Laboratory Director and the Lead Medical Technologist and email correspondence with the Lead Medical Technologist, the laboratory failed to ensure that the established quality assessment program detected, corrected and documented quality assessment activities when failures of quality occurred. Findings include: 1. There were no records available of calibration and maintenance of the automatic pipettes since October, 2019. 2. There were no records of blood bank refrigerator and blood bank freezer alarm checks for 2020 and 2021. 3. There were no records of the twice per year comparison of the instrument results for the Dimension EXL 200 and Dimension EXL LM chemistry analyzers available for 2020 and 2021 for comprehensive metabolic panel, cardiac markers, lipid panel, magnesium and lipase tests performed on both analyzers to verify that each instrument produces consistent results that are accurate and reliable. 4. There were no records of the twice per year comparison of the instrument results for the Sysmex XN-450 and Sysmex XN-550 hematology analyzers available for 2020 and 2021 for the Complete Blood Counts (CBC) performed on both analyzers to verify that each instrument produces consistent results that are accurate and reliable. 5. There were no records of the twice per year comparison of the instrument results for the Sysmex CS-2500 and Sysmex CA-600

coagulation analyzers available for 2020 and 2021 for the prothrombin time (Protime) and activated Partial Thromboplastin Time (aPTT) performed on both analyzers to verify that each instrument produces consistent results that are accurate and reliable. 6. The director approved policy and procedure entitled, "Instruments Methodology Comparison of Test Results" stated, "It is the policy of Desert View Hospital Laboratory, at the interval of every six months, to compare two production instruments that are expected to produce the same quantitative result." 7. The findings were confirmed during an interview with the Laboratory Director and the Lead Medical Technologist on April 19, 2022, and via email correspondence with the Lead Medical Technologist on April 21, 2022 and April 26, 2022. The laboratory performs approximately 186 Microbiology, 260,402 Chemistry, 163,410 Hematology, and 705 Immunohematology tests annually.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on a review of the CASPER D155 report, a review of the 2021 American Proficiency Institute (API) Chemistry Core Proficiency Testing (PT) test event three, and an interview with the Laboratory Director and the Lead Medical Technologist, the director failed to ensure that the laboratory returned the proficiency testing results prior to the deadline established by the proficiency testing agency. (Refer to D6090) Based on a review of the 2020, 2021, and 2022 American Proficiency Institute (API) Proficiency Testing (PT) records, and an interview with the Laboratory Director and the Lead Medical Technologist, the director failed to ensure that all proficiency testing reports were reviewed to evaluate the laboratory's performance and to perform corrective action for all unacceptable results obtained. (Refer to D6091) Based on a review of the director approved policy and procedure entitled "Quality Assurance," a review of the 2020 and 2021 documented quality assessment activities, the lack of availability of the instrument comparison records for the Dimension chemistry analyzers, the Sysmex hematology analyzers, and the Sysmex coagulation analyzers, the lack of records for the pipette calibrations for 2020 and 2021, the lack of records of the 2020 and 2021 blood bank refrigerator and blood bank freezer alarm checks, the failure to review, evaluate, and perform corrective action for the unacceptable proficiency testing results for the API PT 2020, 2021, and 2022 test events, the failure to document initial personnel training and competency assessment prior to the performance of testing, and an interview with the Laboratory Director and the Lead Medical Technologist, the director failed to ensure that the established program of quality assessment was maintained to identify and correct failures in quality of the laboratory services provided when they occurred.(Refer to D6094) Based on a review of personnel initial training and competency assessment documentation, a review of the director approved policy and procedure entitled, "Competency Assessment of Technical Personnel," a review of the completed CMS-209 form, and an interview with the Laboratory Director and the Lead Medical Technologist, the director failed to ensure that initial training and competency assessment was performed and documented prior to testing specimens. (Refer to D6102)

D6090

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(ii)

The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on a review of the CASPER D155 report, a review of the 2021 American Proficiency Institute (API) Chemistry Core Proficiency Testing (PT) test event three, and an interview with the Laboratory Director, the director failed to ensure that the laboratory returned the proficiency testing results prior to the deadline established by the proficiency testing agency. Findings include: 1. A review of the CASPER D155 report revealed that the laboratory obtained a score of zero for the 2021 API PT Chemistry Core test event three. 2. A review of the laboratory records for the 2021 API chemistry core PT test event three revealed that the laboratory had failed to submit the test results to API prior to the deadline of September 15, 2021. 3. The Laboratory Director stated that the tests had been performed, but that the results were not submitted prior to the deadline during an interview conducted on April 19, 2022 at approximately 10:00 AM. The laboratory performs approximately 260,402 Chemistry tests annually.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

Based on a review of the 2020, 2021, and 2022 American Proficiency Institute (API) Proficiency Testing (PT) records, and an interview with the Laboratory Director and the Lead Medical Technologist, the director failed to ensure that all proficiency testing reports were reviewed to evaluate the laboratory's performance and to perform corrective action for all unacceptable results obtained. Findings include: 1. A review of the 2020 API Chemistry Core PT event three revealed that the laboratory did not perform and document corrective action for the Troponin I results for specimen numbers CM-13 and CM-15. The Troponin I reported result for specimen CM-13 was 11.04 nanograms/milliliter (ng/ml). The acceptable range for this specimen was 8.39-10.77 ng/ml. The Troponin I reported for specimen CM-15 was 5.31 ng/ml. The acceptable range for CM-15 was 4.06-5.28 ng/ml. 2. A review of the 2020 API Chemistry Core PT event three revealed that the laboratory did not perform and document corrective action for the Carbon dioxide (CO₂) results for specimen numbers CH-11, CH-13 and CH-14. The CO₂ reported result for specimen CH-11 was 24 millimoles/liter (mmol/L). The acceptable range for this CH-11 was 27-39 mmol/L. The CO₂ reported result for specimen CH-13 was 24 mmol/L. The acceptable range for this CH-13 was 28-40 mmol/L. The CO₂ reported result for specimen CH-14 was 21 mmol/L. The acceptable range for this CH-14 was 23-34 mmol/L. 3. A review of the 2021 API Chemistry Core PT event one revealed that the laboratory did not perform and document corrective action for the Troponin I results for specimen numbers CM-02 and CM-05. The Troponin I reported result for specimen CM-02 was 4.10 ng/ml. The acceptable range for specimen CM-02 was 2.98-3.99 ng/ml. The Troponin I reported for specimen CM-05 was 8.41 ng/ml. The

acceptable range for specimen CM-05 was 6.19-8.19 ng/ml. 4. A review of the 2021 API Chemistry Core PT event one revealed that the laboratory did not perform and document corrective action for the calcium result for specimen number CH-04. The calcium reported result for specimen CH-04 was 11.5 milligrams/deciliter (mg/dl). The acceptable range for specimen CH-04 was 11.7-13.8 mg/dl. 5. A review of the 2021 API Chemistry Core PT event one revealed that the laboratory did not perform and document corrective action for the low density lipoprotein (LDL) result for specimen number CH-02. The LDL reported result for specimen CH-02 was 168 mg /dl. The acceptable range for specimen CH-02 was 144-167 mg/dl. 6. A review of the 2021 API Chemistry Core PT event one revealed that the laboratory did not perform and document corrective action for the Sodium result for specimen number CH-04. The sodium reported result for specimen CH-04 was 153 mmol/L. The acceptable range for specimen CH-04 was 160-169 mmol/L. 7. A review of the 2021 API Chemistry Core PT event one revealed that the laboratory did not perform and document corrective action for the Quantitative Human Chorionic Gonadotropin (HCG) result for specimen number HCG-03. The reported result for specimen HCG-03 was 2259.0 milli-international units/milliliter (mIU/ml). The acceptable range for specimen HCG-03 was 2398.5-3681.4 mIU/ml. 8. A review of the 2022 API Chemistry Core PT event one revealed that the laboratory did not perform and document corrective action for the alcohol result for specimen ALC-01. The reported result for specimen ALC-01 was 138 mg/dl. The acceptable range for specimen ALC-01 was 154-258 mg/dl. 9. A review of the 2022 API Chemistry Core PT event one revealed that the laboratory did not perform and document corrective action for the brain natriuretic peptide (BNP) result for specimen CM-04. The reported result for specimen CM-04 was 150 picograms/milliliter (pg/ml). The acceptable range for specimen CM-04 was 113-144 pg/ml. 10. A review of the 2022 API Chemistry Core PT event one revealed that the laboratory did not perform and document corrective action for the creatine kinase (CK) results for specimens CH-01 and CH-02. The reported result for specimen CH-01 was 229 Units/Liter (U/L). The acceptable range for specimen CH-01 was 14-27 U/L. The reported result for specimen CH-02 was 69 U/L. The acceptable range for specimen CH-02 was 246-458 U/L. 11. A review of the 2022 API Chemistry Core PT event one revealed that the laboratory did not perform and document corrective action for the Quantitative Human Chorionic Gonadotropin (HCG) result for specimen numbers HCG-01 and HCG-04. The reported result for specimen HCG-01 was 2397.0 mIU/ml. The acceptable range for specimen HCG-01 was 4560.0-7049.1 mIU/ml. The reported result for specimen HCG-04 was 2573.0 mIU/ml. The acceptable range for specimen HCG-04 was 2646.7-4203.2 mIU/ml. 12. There was no documentation of a review of the data summary for the API PT 2020 Hematology/Coagulation test event three for the blood cell identification of Specimen BCI-11, which was ungraded due to lack of consensus. 13. There was no documentation of a review for the API PT 2020 Hematology/Coagulation test event three of the ungraded Educational Blood Cell Identification samples ECI-11, ECI-12, ECI-13, ECI-14 and ECI-15. 14. There was no documentation of a review of the data summary for the API PT 2020 Hematology/Coagulation test event for the urine sediment result for specimen number US-06, which was ungraded due to lack of consensus. 15. There was no documentation of a review of the data summary for the API PT 2021 Hematology/Coagulation test event for the blood cell identification of Specimen BCI-07, which was ungraded due to lack of consensus. 16. There was no documentation of a review for the API PT 2021 Hematology/Coagulation test event two of the ungraded Educational Blood Cell Identification samples ECI-06, ECI-07, ECI-08, ECI-09, and ECI-10. 17. The findings were confirmed during an interview with the Laboratory Director and the Lead Medical Technologist during an interview conducted on April 19, 2022 at approximately 11:00 AM. The laboratory performs

approximately 260,402 Chemistry and 163,410 hematology tests annually.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on a review of the director approved policy and procedure entitled "Quality Assurance," a review of the 2020 and 2021 documented quality assessment activities, the lack of availability of the instrument comparison records for the Dimension chemistry analyzers, the Sysmex hematology analyzers, and the Sysmex coagulation analyzers, the lack of records for the pipette calibrations for 2020 and 2021, the lack of records of the 2020 and 2021 blood bank refrigerator and blood bank freezer alarm checks, the failure to review, evaluate, and perform corrective action for the unacceptable proficiency testing results for the API PT 2020, 2021, and 2022 test events, the failure to document initial personnel training and competency assessment prior to the performance of testing, and an interview with the Laboratory Director and the Lead Medical Technologist, the director failed to ensure that the established program of quality assessment was maintained to identify and correct failures in quality of the laboratory services provided when they occurred. Findings include: 1. The director approved policy and procedure entitled, "Quality Assurance" stated in the section entitled, "Procedure" in step A, "Proficiency Testing results are reviewed by the testing personnel, the Technical Supervisor, and the Lab Director (or Lab Director's designee). Investigation is made as to root cause for failed challenges and unsuccessful performances. Corrective action is taken when indicated and monitored to ensure the resolution of the problem." 2. The director approved policy and procedure entitled, "Quality Assurance" stated in the section entitled, "Procedure," in Step F, "The laboratory has a process established to assess employee technical competence and ensure employees maintain technical competence to perform all duties authorized by the Lab Director." 3. The established quality assessment program did not detect and correct the failure to perform the annual calibrations of the automatic pipettes in 2020 and 2021. 4. The established quality assessment program did not detect and correct the failure to perform the quarterly blood bank refrigerator alarm checks, and the periodic blood bank freezer alarm checks in 2020 and 2021. 4. The established quality assessment program did not detect and correct the failure to ensure that the instrument comparisons were performed, evaluated for acceptability, and available for review for the Dimension EXL LM and Dimension EXL 200 chemistry analyzers, the Sysmex XN-450 and Sysmex XN-550 hematology analyzers, and the Sysmex CS-2000 and CA-600 coagulation analyzers. 5. The findings were confirmed during an interview with the Laboratory Director and the Lead Medical Technologist on April 19, 2022 at approximately 3:00 PM, and via email correspondence with the Lead Medical Technologist on April 21, 2022. The laboratory performs approximately 186 Microbiology, 260,402 Chemistry, 163,410 Hematology, and 705 Immunohematology tests annually.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all

personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of personnel initial training and competency assessment documentation, a review of the director approved policy and procedure entitled, "Competency Assessment of Technical Personnel," a review of the completed CMS-209 form, and an interview with the Laboratory Director and the Lead Medical Technologist, the director failed to ensure that initial training and competency assessment was performed and documented prior to testing specimens. Findings include: 1. A review of the training and competency assessment documents for five of 33 testing personnel revealed that the initial training and competency assessments were not completed prior to the performance of testing. 2. Personnel numbers three, four, and five listed on the CMS-209 form, each with hire dates of September, 2021 did not complete documentation of initial training and competency assessment until April 12, 2022 for the Sysmex hematology and coagulation instruments, the Siemens Dimension EXL chemistry instruments, the immunohematology procedures for ABO and Rh blood typing, antibody screening, and compatibility testing, and the microbiology procedures of gram stains and Clostridium difficile toxin testing. 3. Personnel numbers 17 and 34 did not complete the documentation of initial training and competency assessment in the performance of arterial blood gas testing on the Radiometer ABL 80 instruments prior to the performance of testing. Personnel number 17 listed on the CMS-209 form performed patient testing on April 9, 2022. The documentation of initial training and competency assessment was completed on April 15, 2022. Personnel number 34 listed on the CMS-209 form performed patient testing on March 12, 2022. The documentation of training and competency assessment was completed on April 5, 2022. 4. The director approved policy and procedure entitled, "Competency Assessment of Technical Personnel," in the section entitled, "Procedure," stated, "1. The Laboratory Director ensures that policies and procedures are established for assessing competency of all technical staff covering all phases of laboratory testing. This may be delegated in writing to the Technical Supervisor. The Laboratory Manager/Technical Supervisor evaluates all competency assessments to ensure staff proficiency in testing. This evaluation is done every 6 months for the first year of employment, the annually thereafter." The completed CMS-209 form indicated that the Laboratory Director also fulfills the duties of the Technical Supervisor. 5. The Laboratory Director and the Lead Medical Technologist confirmed the findings during an interview conducted on April 19, 2022 at approximately 12:00 PM. The laboratory performs approximately 186 Microbiology, 260,402 Chemistry, 163,410 Hematology, and 705 Immunohematology tests annually.