| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 45D1010541 | 02/15/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Silsbee Family Medicine, Pa | 280 Hwy 418 East, Silsbee, TX | |

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** | Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. |
| **D5213** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(1)<br><br>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's American Proficiency Institute's (API) proficiency testing (PT) records from 2020 and 2021, review of the API's form Performance Review and Corrective Action Documentation and staff interview it was determined the laboratory failed to perform the required self-evaluation for 1 of 6 reviewed Urine Sediment results and 1 of 6 reviewed Vaginal Wet Preparation (KOH) results for which performance was not graded. Findings included: 1. Review of the laboratory's API PT records from 2020 (events 1, 2, and 3) and 2021 (events 1, 2, and 3) revealed the following analytes for which performance was not graded: 2020 Hematology /Coagulation, Event 3; Analyte: Urine Sediment Expected Results: See Data |

| | |
|---|---|
| | Summary Performance: Not Graded 2021 Hematology/Coagulation, Event 3; Analyte: Vaginal Wet Preparation (KOH) Expected Results: See Data Summary Performance: Not Graded 2. Review of API form titled "Performance Review and Corrective Action Documentation" revealed: "Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 3. Further review of the laboratory's API PT records revealed there was no documentation of self-evaluation of the above "Not graded" results. 4. In an interview on 02/15/2022 at 1040 hours in the break room Testing Person #2 (as described on Form 209 signed by laboratory director on 02/15/2022) confirmed the findings. Legend: KOH = Potassium hydroxide |
| **D5215** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(2)<br><br>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).<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's American Proficiency Institute's (API) proficiency testing (PT) records from 2020 and 2021 and staff interview, it was determined the laboratory failed to have documentation of performing corrective action for unacceptable scores for Vaginal Wet Preparation for 1 of 6 events reviewed. The findings were: 1. A review of the laboratory's API proficiency testing records from 2020 (events 1, 2, and 3) and 2021 (events 1, 2, and 3) revealed the laboratory failed to attain a satisfactory score of at least 80% for the analyte vaginal wet preparation for 1 of 6 events reviewed: 2021 Hematology/Coagulation, Event 1; Analyte: Vaginal Wet Preparation Score: 0% Performance: Unacceptable 2. Review of API form titled " Performance Review and Corrective Action Documentation " for 2021 Hematology /Coagulation, Event 1, signed and dated by the laboratory director on 6-22-20 (sic), revealed there was no documentation of corrective action for the unacceptable score for Vaginal Wet Preparation. 3. In an interview on 02/15/2022 at 1050 hours in the break room Testing Person #2 (as described on Form 209 signed by laboratory director on 02/15/2022) confirmed the findings. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies for hematology, review of the Drew3 hematology analyzer operator's manual, review of Complete Blood Count (CBC) patients' test instrument printouts and final reports and staff interview it was determined the laboratory failed to address flagged test results as per manufacturer requirements for 9 of 20 patient reports reviewed. Findings included: 1. Review of the laboratory's policies for hematology revealed there was no policy for addressing flagged CBC test results obtained from the Drew3 hematology analyzer. 2. Review of the laboratory's Drew3 hematology analyzer operator's manual (M-Drew3-US-OP-Rev 1.06) under section 9.5.2 Leukocyte Flags revealed: "L2 = CL 2 to CL2-2: Possible presence of Myelocytes, lymphoblasts or basophiles; increased monocyte count. L3 = CL2 to CL3: Possible presence of eosinophiles or myelocytes. L4 = CL4 Granulocyte volume below average" And, "The hematology flags listed above are non-specific and the meaning of each message is only a suggestion of the cause of a possible abnormality. Always verify flagged WBC distributions according to your laboratory's protocol" 3. Review of the laboratory's patients' test instrument printouts and final reports revealed the following flagged patient's results (9 of 20 reviewed) were reported to provider without documentation of WBC distribution verification: Patient: 16088 Sample: 00024 Tested: 02/14/2022 at 06:02:07PM - results contained L2, L3 and L4 flags Instrument Final Printout: report: LYM% - 28.9% Lymphs: 28.9% MID% - 12% Mono size: 12.0% GRA% - 59.1% Segs: 59.1% Patient: 20590 Sample: 00025 Tested: 02/14/2022 at 06:09:42PM - results contained L3 flag Instrument Final Printout: report: LYM% - 7.9% Lymphs: 7.9% MID% - 9.1% Mono size: 9.1% GRA% - 83.0% Segs: 83.0% Patient: 7920 Sample: 00026 Tested: 02/14 /2022 at 06:17:56PM - results contained L2, L3 and L4 flags Instrument Final Printout: report: LYM% - 15.5% Lymphs: 15.5% MID% - 11.3% Mono size: 11.3% GRA% - 73.2% Segs: 73.2% Patient: 13645 Sample: 00027 Tested: 02/14/2022 at 06: 23:14PM - results contained L2, L3 and L4 flags Instrument Final Printout: report: LYM% - 10.3% Lymphs: 10.3% MID% - 13.4% Mono size: 13.4% GRA% - 76.3% Segs: 76.3% Patient: 2809 Sample: 00028 Tested: 02/14/2022 at 06:45:23PM - results contained L2, L3 and L4 flags Instrument Final Printout: report: LYM% - 15.5% Lymphs: 15.5% MID% - 11.3% Mono size: 11.3% GRA% - 73.2% Segs: 73.2% Patient: 20513 Sample: 00029 Tested: 02/14/2022 at 07:05:21PM - results contained L3 flag Instrument Final Printout: report: LYM% - 17.5% Lymphs: 17.5% MID% - 9.8% Mono size: 9.8% GRA% - 72.7% Segs: 72.7% Patient: 20557 Sample: 00030 Tested: 02/14/2022 at 07:09:35PM - results contained L2, L3 and L4 flags Instrument Final Printout: report: LYM% - 50.0% Lymphs: 50.0% MID% - 13.0% Mono size: 13.0% GRA% - 37.0% Segs: 37.0% Patient: 20646 Sample: 00031 Tested: 02/14 /2022 at 07:15:24PM - results contained L2, L3 and L4 flags Instrument Final Printout: report: LYM% - 34.5% Lymphs: 34.5% MID% - 19.4% Mono size: 19.4% GRA% - 46.1% Segs: 46.1% Patient: 10499 Sample: 00032 Tested: 02/14/2022 at 07: 23:46PM - results contained L2, L3 and L4 flags Instrument Final Printout: report: LYM% - 42.5% Lymphs: 42.5% MID% - 14.5% Mono size: 14.5% GRA% - 43.0% Segs: 43.0% 4. In an interview on 02/15/2022 at 1130 hours in the break room Testing Person #2 (as described on Form 209 signed by laboratory director on 02/15/2022)

| | |
|---|---|
| | stated that she was unaware that the laboratory had to have a protocol for WBC distribution verification for flagged results. This confirmed the findings. Legend: LYM /Lymphs = Lymphocytes MID/Mono size = Monocytes GRA/Segs = Granulocyte WBC = White Blood Cells |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the manufacture's instructions for use for the EX-TROL hematology controls (AISD05-011 Rev. 02/17), review of the laboratory's temperature charts from December of 2021 to February 15 of 2022 and staff interview it was determined the laboratory failed to store EX-TROL hematology controls according to manufacturer instructions on 53 of 53 days reviewed. Findings included: 1. Review of the manufacture's Instructions for Use (for the EX-TROL hematology controls (Lot# EX0122 Expiration date; 2022-04-05 stored in the laboratory's refrigerator) revealed the kit's unopened component storage requirements were as follows: "Store up-right between 2C to 8C(36F to 46F) when not in use." 2. Review of the laboratory's temperature charts from December of 2021 to February 15th of 2022 revealed: a. The laboratory established refrigerator temperature range as "=2-8C" b. The laboratory documented refrigerator temperature as -2C for 53 of 53 days temperature was monitored. 3. In an interview on 02/15/2022 at 1245 hours in the break room Testing Person #2 (as described on Form 209 signed by laboratory director on 02/15/2022) stated that she was unaware that the laboratory was recording temperature outside of the required range. This confirmed the findings. |
| **D5469** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(10)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by: |

| | |
|---|---|
| | Based on review of the laboratory's quality control (QC) records for the Drew3 hematology analyzer form April to December of 2021, review of the laboratory's records for verification of new lots of hematology EX-TROL controls and staff interview it was determined the laboratory failed to document verification of new control lots with concurrent testing for 3 of 4 lot changes reviewed. Findings included: 1. Review of the laboratory's quality control (QC) records for the Drew3 hematology analyzer form April to December of 2021 revealed the laboratory implemented new hematology controls as follows: Control Lot: EX0421 Expiration: 2021-07-05 Testing dates: 04/01/2021 to 06/30/2021 There was no documentation of concurrent testing with the previous lot. Control Lot: EX0721 Expiration: 2021-10-05 Testing dates: 07 /02/2021 to 09/30/2021 There was no documentation of concurrent testing with the previous lot. Control Lot: EX1021 Expiration: 2022-01-05 Testing dates: 10/01/2021 to 12/30/2021 There was no documentation of concurrent testing with the previous lot. 2. The laboratory was asked to provide documentation of new controls' lot verification for the above lots and no such documentation was provided. 3. In an interview on 02/15/2022 at 1230 hours in the break room Testing Person #2 (as described on Form 209 signed by laboratory director on 02/15/2022), after review of the data, confirmed the findings. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Drew3 hematology analyzers' manufacturer instructions for flagged results, review of quality control temperature logs, review of new lot verification studies and staff interview it was determined the laboratory's Quality Assessment failed to identify and correct problems identified in the analytic systems. Findings included: 1. The laboratory's quality assessment failed to ensure the laboratory addressed Drew3 hematology analyzers' flagged results as per manufacturer requirements (refer to D5403). 2. The laboratory's quality assessment failed to ensure hematology controls' storage temperature was maintained as required (refer to D5413). 3. The laboratory's quality assessment failed to ensure new lot verification of hematology controls was documented with concurrent testing (refer to D5469). |