| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 49D2066154 | 11/16/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Sovah Internal Medicine (Pim) | 125 Executive Drive - Suite H, Danville, VA | |

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 |
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| **D0000** | An announced CLIA recertification survey was conducted at SOVAH Internal Medicine PIM on November 16, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows: |
| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to rotate PT among the two (2) personnel performing Complete Blood Count (CBC) patient testing during the twenty-six (26) months reviewed. Findings include: 1. Review of the CMS 209 form revealed 2 testing personnel (TP) performed CBC patient testing on the Medonic hematology analyzer during the inspection review timeframe of August 2019 to 11/16/21. 2. Review of the laboratory's American Proficiency Institute (API) PT records, a total of six (6) events (2019 Event 3, 2020 Events 1- 2 noted: laboratory testing was suspended event 3, and 2021 Events 1-3) revealed: TP A signed attestations /performed 6 of the 6 API hematology PT events outlined above. (See Personnel Code Sheet.) 3. In an exit interview with the lead testing personnel on 11/16/21 at approximately 2:00 PM, the above findings were confirmed. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1) |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to verify twice annual accuracy of urinalysis sediment microscopy in calendar year 2019. Findings include: 1. During a laboratory tour on 11 /16/21 at approximately 11 AM, the inspector noted a microscope stored in the laboratory and inquired regarding the use of the microscope. The primary testing personnel stated: "We do very few urine microscopics in our lab. We send almost all of them out but occasionally our doctor wants one done." 2. Review of the laboratory's American Proficiency Institute (API) Urine Microscopy module PT records (2019 Events 2-3, 2020 Events 1-3, 2021 Events 1-2) revealed the following unsatisfactory scores: 2019 Event 2- 50%; 2019 Event 3 - 50%; 2020 Event 1 - 50% - long term unsuccessful performance noted by API; 2021 Event 2 - 50%. The inspector requested to review documentation of corrective action for the four unsatisfactory scores outlined above and additional accuracy checks for calendar year 2019. No documentation was available for review. 3. In an exit interview with the lead testing personnel on 11/16/21 at approximately 2:00 PM, the above findings were confirmed. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of instrument maintenance logs, manufacturer's operations manual, lack of documentation, and an interview, the laboratory failed to document performance of required monthly hematology analyzer maintenance protocols for four (4) of twelve (12) months in calendar year 2020 and three (3) of ten (10) months reviewed in calendar year 2021. Findings include: 1. A review of the laboratory's Medonic hematology analyzer's maintenance logs (January 2020 to 11/16/21) revealed two required monthly tasks: Cap Piercer (CP) Clean and CP- Clot Prevention. The inspector noted that no documentation of the above maintenance was recorded in the following months: Calendar year 2020: January, February, March, November; Calendar year 2021: June, July, October. The inspector inquired regarding the lack of documentation and to review corrective action. No documentation was available for review. 2. Review of the Medonic operations manual revealed manufacturer's maintenance instructions (on page 65) related to the monthly cleaning protocols outlined above: Monthly Cleaning: "The monthly cleaning procedure is to secure the correct function of the instrument and should be done on a monthly basis." Clot Prevention: "This process will decrease the risk of debris material building up in the instrument system. This should be performed at least once a month." 3. In an exit interview with the lead testing personnel on 11/16/21 at approximately 2:00 PM, the above findings were confirmed. |
| **D5437** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(a) |

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| | Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of procedures, hematology calibration records, and an interview, the laboratory failed to document calibration procedures every six (6) months for hematology Complete Blood Count (CBC) testing according to their written procedure in calendar year 2020 and 2021. Findings include: 1. Review of the laboratory's procedure manual revealed a Hematology Quality Control (QC) policy that outlined to calibrate the CBC testing on the Medonic hematology analyzer at a frequency of every 6 months. The policy stated: "Analyzer is to be calibrated every six months with calibrators for the Medonic M Series". 2. Review of the hematology instrument calibration documentation from January 2020 to the date of the inspection on 11/16/21, a total of twenty-two (22) months, revealed calibrations were performed twice: in October 2020 and October 2021. The inspector noted that the two documented Medonic calibrations, outlined above, were performed by a Cardwell Medical field service specialist. The inspector requested to review additional calibration records. No additional calibration documentation was available. 3. In an exit interview with the lead testing personnel on 11/16/21 at approximately 2:00 PM, the above findings were confirmed. |