

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0466059	(X3) Date Survey Completed 09/25/2019
Name of Provider or Supplier Mountain View Clinic Inc	Street Address, City, State 1102 Crestwood Circle, Mena, AR	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: . Through a review of the laboratory policy and procedure manual, manufacturer's instruction for Sysmex XP-300 Hematology Analyzer, patient results, lack of documentation and interview with laboratory personnel, it was determined the laboratory failed to follow its own policy for resolving flags prior to their release to the healthcare provider. As evidenced by: A. A review of the laboratory policy for Histogram Flags revealed "When the Histogram Flags are displayed, perform the analysis again. If after the repeat analysis the flags are still displayed, the sample is considered to correspond to the "Probable Sample Cause" listed on page 8-21 and 8-22 of the Sysmex XP-300 Operators Manual. B. A review of manufacturer's instruction for the Sysmex XP-300 Hematology analyzer page 8-21 and 8-22 under the section "Flagging Summary" revealed the manufacturer identified the following flags and possible actions for: Differentials: Flag [WL]: Probable cause: Incomplete lysing of red cells, presence of nucleated red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation or fibrin. Correction: [1] Centrifuge the sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, [2] Check smear. Flag [T1]: Probable cause: Presence of Chronic Myelogenous Leukemia (CML) or other immature Granulocytes, incomplete lysing of red blood cells. Correction: [1] Check smear [2] Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37 degrees Celsius for 30 minutes and repeat analysis. Flag [T2]: Probable Cause: Presence of CML or other immature Granulocytes, incomplete lysing of red blood</p>

cells, aged sample. Correction: [1] Check smear, [2] Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37 degrees Celsius for 30 minutes and repeat analysis. Platelet Flags: Flag [AG]: Probable cause: Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Correction: Check smear. C. In an interview on 9/25/2019 at 1430, the technical consultant confirmed the laboratory does not perform manual differentials or slide review. If after repeat analysis the histogram flags are present, the sample should be verified by the reference laboratory. D. A review of patient Complete Blood Count (CBC) results revealed ten of twenty-five patients result had flags that were not resolved prior to their release to the healthcare provider. Patient #10109453 Flag: AG and T2 No repeat analysis performed specimen was not sent to reference laboratory for verification. Patient #10109463 Flag: AG No repeat analysis performed specimen was not sent to reference laboratory for verification. Patient #1019467 Flag: AG No repeat analysis performed specimen was not sent to reference laboratory for verification. Patient #10109517 Flag: AG No repeat analysis performed specimen was not sent to reference laboratory for verification. Patient #1019542 Flag: AG No repeat analysis performed specimen was not sent to reference laboratory for verification. Patient #10109545 Flag: WL and AG No repeat analysis performed specimen was not sent to reference laboratory for verification. Patient #10109547 Flag: AG No repeat analysis performed specimen was not sent to reference laboratory for verification. Patient #10109430 Flag: AG No repeat analysis performed specimen was not sent to reference laboratory for verification. Patient #10109439 Flag: AG No repeat analysis performed specimen was not sent to reference laboratory for verification. Patient 1019363 Flag: AG No repeat analysis performed specimen was not sent to reference laboratory for verification. E. The Surveyor asked for documentation of resolving the flags prior to their release to healthcare provider. No documentation was provided. F. In an interview on 9/25/2019 at 1500, technical consultant confirmed the findings and that the specimens were not sent to the reference laboratory for verification.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
 CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
 . Through a review of the new instrument Verification Studies, which was performed on 08/20/2019 for the Ortho Clinical Diagnostics Vitros 350, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to verify the reportable range established by the manufacturer for three of nineteen Chemistry Analytes verified on the Ortho Clinical Diagnostics Vitros Chemistry Analyzer. As evidenced by: A. A review of the Ortho Clinical Diagnostics analytical measurement range study for three of nineteen analytes revealed the reportable ranges for Total Bilirubin (TBILI) as 0.1 to 27, Triglycerides (TRIG) 10 to 525 and Alkaline Phosphatase (ALKP) 20 to 1500. B. A review of the Ortho Clinical Diagnostics

analytical measurement range study dated 8/21/2019 include the following ranges verified by testing standard solutions: TBILI 1.1 to 17.14, TRIG 26.4 to 474.3 and ALKP 20 to 1250.5. The laboratory did not verify the full analytic range established by the manufacturer. C. In an interview on 9/25/2019 at 14:00 on the technical consultant confirmed the laboratory did not verify the full reportable range established by the manufacturer for the Ortho Clinical Diagnostic Vitros 350 Chemistry Analyzer.