

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2086145	(X3) Date Survey Completed 03/05/2020
Name of Provider or Supplier Healthcare Express - Maumelle	Street Address, City, State 11819 Maumelle Blvd, Maumelle, 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:</p> <p>. 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. A. A review of the laboratory's policy and procedure manual for Complete Blood Count (CBC) revealed the policy for Resolving CBC Flags: "Flags occur occasionally when performing CBC. Flags indicate that there was a problem with the measurement of that particular parameter. These flags must be resolved before patient results can be reported. For Platelet (PLTS) Flag: PL, PU, MP, DW and AG: Remix the sample by gentle inversion and repeat. If Flags are still present: Do not report results. Send sample to reference laboratory." B. A review of patient Complete Blood Count (CBC) results revealed three of ten patients result, had PLT flags that were not resolved prior to their release to the healthcare provider. Patient # 02171999 Flag: AG No repeat analysis performed specimen was not sent to reference laboratory. Patient #05021966 Flag: AG No repeat analysis performed specimen was not sent to reference laboratory. Patient #1017969 Flag: AG No repeat analysis performed specimen was not sent to reference laboratory. C. The Surveyor asked for documentation of resolving the flags prior to release of results to healthcare provider. No documentation was provided. D. In an interview on 03/05/2020 at 11:30, technical consultant confirmed the findings and that the specimens were not sent to the reference laboratory for confirmation.</p>