

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0939515	(X3) Date Survey Completed 09/01/2022
Name of Provider or Supplier Southeast Medical Group	Street Address, City, State 1612 Highway 78 East, Suite 100, Oxford, AL	
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: Based on a review of the Procedure Manual and an interview with the Office Administrator, the laboratory failed to have a written procedure for the Emerald Cell Dyn Hematology analyzer. The findings include: 1. A review of the Procedure Manual revealed a lack of written procedures for the Emerald Cell Dyn Hematology analyzer. 2. During an interview on 09/01/2022 at 4:00 PM, the Office Administrator confirmed the laboratory did not have any other procedures available.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Testing Personnel records and an interview with the Office Administrator, the Technical Consultant failed to implement and document evaluations that included the six minimal regulatory requirements for assessment of competency on the Emerald Cell Dyn Hematology analyzer. This was noted for ten out of ten Testing Personnel from December 2020 to the date of the current survey (09</p>

/01/2022). The findings include: 1. A review of Testing Personnel records revealed the competency assessments did not include the six minimal regulatory requirements for assessment of competency as specified by CLIA. The aforementioned document only included a statement deeming the Testing Personnel competent, with the signature of the employee and the Laboratory Supervisor. 2. During an interview at 10:48 AM on 09/01/2022, the Office Administrator stated, "The yearly evaluations are completed based on a review of the Emerald training checklist".