Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2091573	02/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Southeast Clinical Laboratories	3621 3rd Ave South, Birmingham, 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
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: Based on reviews of the installation and validation records for four new instruments in the specialty of Microbiology and interviews with the Microbiology General Supervisor and the Laboratory Director, the surveyor determined the laboratory failed to ensure an evaluation of the data generated during the initial installation procedures was documented, reviewed and approved as verification of the manufacturer's performance specifications for precision and accuracy before patient testing began. The laboratory further failed to ensure discrepant results generated during the validation were investigated to determine if further studies or other corrective actions were required. The findings include: (I) BD Max analyzer--used for the qualitative detection of Neisseria gonorrhoeae, Chlamydia trachomatis, and Trichomonas vaginalis 1. A review of the installation and validation records for the BD Max analyzer revealed results reports from 29 known specimens tested on 10/2/2018 with a graph of the positive/negative results generated from the studies. However, there was no documentation the data was analyzed and evaluated to verify the precision and accuracy as per manufacturer's performance specifications before patient testing began on 10/29/2018; there was also no documentation of the Laboratory Director's review and approval (as indicated by his signature and date) on the initial verification procedures. 2. In an interview on 2/21/2019 at 9:42 AM, the above noted findings

were reviewed and confirmed with the Microbiology General Supervisor. (II) Thunderbolt analyzer--used with the TB QuantiFERON Gold kit for the qualitative detection of Mycobacterium tuberculosis 1. A review of the installation and validation records for the Thunderbolt / TB QuantiFERON Gold kit revealed the testing of 44 known specimens was originally performed on 8/9-8/10/2017. However, there was no documentation the data was analyzed and evaluated to verify the precision and accuracy as per manufacturer's performance specifications before patient testing began in August 2017; there was also no documentation of the Laboratory Director's review and approval (as indicated by his signature and date) on the initial verification procedures. 2. A further review of the data by the surveyor revealed the laboratory obtained negative results for two known positive samples, however there was no documentation of investigation to determine the cause of the discrepant results to determine if further studies or other corrective actions were required. 3. In an interview on 2/21/2019 at 10:08 AM, the above noted findings and discrepancies in the validation studies were reviewed and confirmed with the Microbiology General Supervisor who stated the company (Qiagen) had emailed a notification concerning the two positive samples that were yielding the negative results. However, the laboratory failed to document a follow-up review of the Thunderbolt validation, or provide a copy of the email notification for review. (III) BioFire Film Array 2.0--used for the qualitative PCR (Polymerase Chain Reaction) detection of specific organisms in the Respiratory Panel 2 and the GI (Gastrointestinal) Panel 1. A review of the installation and validation records for the BioFire Film Array 2.0 revealed results reports from four pooled samples with known results tested on two consecutive days by two different testing personnel, as follows: A) Respiratory Panel 2 with 18 organisms was tested on 9/26-9/27/2017 B) GI Panel with 22 organisms was tested on 10/10-10/11/2017 However, there was no documentation the data was analyzed and evaluated to verify the precision and accuracy as per manufacturer's performance specifications before patient testing began in October 2017; there was also no documentation of the Laboratory Director's review and approval (as indicated by his signature and date) on the initial verification procedures. 2. A further review by the surveyor revealed both testing personnel detected the presence of Adenovirus F40/41 on Day 2 (10/11/2017) in the Pool 4 sample. (This virus was not on the list of expected results for Pool 4.) There was no documentation of investigation to determine the cause of the discrepant results to determine if further studies or other corrective actions were required. 3. In an interview on 2/21/2019 at 10:50 AM, the above noted findings and discrepancies in the validation studies were reviewed with the Microbiology General Supervisor who confirmed Adenovirus F40/41 was not in Pool 4. The Supervisor further stated the BioFire technical representative stated the validation was all good. The Laboratory Director was also present, and stated the BioFire representative had not mentioned any discrepant results. (IV) BioFire Film Array Torch--used for the qualitative PCR (Polymerase Chain Reaction) detection of specific organisms in the Respiratory Panel 2, the GI Panel, and Blood Pathogen Panel 1. A review of the installation and validation records for the BioFire Film Array Torch revealed results reports from four pooled samples with known results tested on consecutive days by two different testing personnel, as follows: A) Respiratory Panel 2 with 18 organisms: Pool 1 and 2 were tested on 10/18-10/19/2018; Pool 3 and 4 were tested 10/22-10/23/2018 B) GI Panel with 22 organisms: Pool 1 and 2 were tested on 10/18-10/19/2018; Pool 3 and 4 were tested 10/22-10/23/2018 C) Blood Pathogen Panel with 24 organisms: Pool 1 and 2 were tested on 10/11-10/12/2018; Pool 3 and 4 were tested 10/18-10/19/2018 However, there was no documentation the data was analyzed and evaluated to verify the precision and accuracy as per manufacturer's performance specifications before patient testing began in late October 2018; there was also no documentation of the Laboratory Director's review and

	approval (as indicated by his signature and date) on the initial verification procedures. 2. A further review by the surveyor revealed discrepant results in the GI Panel as follows: A) Pool 1/Day 1 (10/18/2018): Tech A detected Norovirus GI/GII (This virus was not on the list of expected results for Pool 1.) B) Pool 2/Day 1: Tech B detected Yersinia enterocolitica (This virus was not on the list of expected results for Pool 2.) There was no documentation of investigation to determine the cause of the discrepant results to determine if further studies or other corrective actions were required. 3. In an interview on 2/21/2019 at 11:15 AM, the above noted findings and discrepancies in the validation studies were reviewed with the Microbiology General Supervisor who confirmed the above organisms were not in the respective pooled samples. 4. During the exit summation on 2/22/2019 at 12:00 PM, the above noted concerns in the Microbiology section were reviewed and confirmed with Technical Supervisor #1 and the Microbiology General Supervisor.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on reviews of the installation and validation records for four new instruments in the specialty of Microbiology and interviews with the Microbiology General Supervisor and the Laboratory Director, the surveyor determined the Laboratory Director failed to document his review and approval of the initial installation procedures as verification of the manufacturer's performance specifications for precision and accuracy before patient testing began. The Director further failed to ensure discrepant results obtained during the validations were investigated to determine if further studies or other corrective actions were required. Refer to D5421 concerning deficiencies in the verification for the following analyzers: BD Max analyzer--used for the qualitative detection of Neisseria gonorrhoeae, Chlamydia trachomatis, and Trichomonas vaginalis Thunderbolt analyzer--used with the TB QuantiFERON Gold kit for the qualitative detection of Mycobacterium tuberculosis BioFire Film Array 2.0--used for the qualitative PCR (Polymerase Chain Reaction) detection of specific organisms in the Respiratory Panel 2 and the GI (Gastrointestinal) Panel BioFire Film Array Torch--used for the qualitative PCR (Polymerase Chain Reaction) detection of specific organisms in the Respiratory Panel 2, the GI Panel, and Blood Pathogen Panel SURVEYOR ID#32558 Licensure and Certification Surveyor