Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0306156	06/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Selma Pediatrics Pc	1225 Medical Center Parkway, Selma, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on a review of CAP (College of American Pathologists) proficiency testing records, a review of the personnel files and CMS form #209 (Laboratory Personnel Report), and an interview with the Laboratory Director (LD), who also serves as the Technical Consultant, the surveyor determined the laboratory failed to ensure proficiency testing was rotated amongst all testing personnel, who performed moderate complexity testing. This affected eight of eight Hematology testing events reviewed by the surveyor. The findings include: 1. A review of the CMS form #209 (the Laboratory Personnel Report) revealed eleven testing personnel. At 11:14 AM on June 20, 2019, the LD stated all personnel listed on this form tested moderate complexity (non-waived) tests, which included the CBC (Complete Blood Counts) on the Medonic. 2. A review of the personnel files revealed only three of the eleven personnel listed were considered new employees since the last survey (June of 2017), and the three were hired in 2019. 3. A review of the proficiency testing records revealed all of the attestation statements for Hematology testing events in 2017 (three events), 2018 (three events) and the first two events in 2019 were signed by Testing Personnel #1 (as the testing personnel). 4. In an interview on 6/20/2019 at 12:18 PM, the surveyor inquired about the performance of the proficiency testing. The LD stated [Testing Personnel (TP) #1] was a part-time employee, and because all of the other nurses were usually assigned, when TP #1 arrived at work, TP#1 was usually assigned to the laboratory. The LD further stated all the other nurses could participate in the proficiency testing, it had been a matter of convenience.

D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the CAP (College of American Pathologists) proficiency testing records, including the attestation statements, and an interview with the Laboratory Director (LD), who also serves as the Technical Consultant, the surveyor determined the Laboratory Director failed to sign the attestation statement for Hematology testing event FH2 A, 2019, one of fifteen testing events reviewed by the surveyor for 2017 - 2019. The findings include: 1. A review of the proficiency testing records revealed the LD did not sign the attestation statement for Hematology testing event FH2-A, 2019. 2. In an interview on 6/20/2019 at 12:18 PM, the LD confirmed he missed signing the attestation statement for the above mentioned event. The LD stated he believed this was the first event the laboratory submitted electronic proficiency testing results, rather than mailing the documentation.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the laboratory's test menu, a review of CAP (College of American Pathologists) proficiency testing records, and an interview with the Laboratory Director (also the Technical Consultant), the surveyor determined the laboratory failed to review and evaluate the results for Microbiology Event MC3-A, 2017, due to the laboratory's failure to obtain the results from the proficiency testing provider. This affected one of seven Microbiology testing events reviewed by the surveyor. The findings include: 1. A review of the proficiency testing records for Microbiology MC3-A, 2017 revealed no result sheet or summary and no review or evaluation returned from CAP. 2. In an interview on June 20, 2019 at 12:11 PM, the Laboratory Director (LD) reviewed the laboratory's records and stated the results were faxed to CAP on April 3 (2017). The LD also confirmed the proficiency testing records did not include any results for the event. At 12:34 PM, after further investigation, the LD stated CAP indicated a code 40 for the laboratory, which meant no results were received by CAP from the laboratory. The LD failed to realize the results were never received by CAP, until the day of the survey.
D5477	CONTROL PROCEDURES

	CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the Uricult and DTM (Dermatophyte Test Medium) Fungal Culture Quality Control (QC) records, a lack of documentation, and an interview with the Laboratory Director (LD), who also serves as the Technical Consultant (TC), the surveyor determined the laboratory failed to perform and document visual inspections of the Acu-DTM media. The laboratory further failed to perform quality control of the Uricult [CLED (Cystine-Lactose Electrolyte Deficient/EMB(Eosin Methylene Blue)] media to verify its ability to support growth and select or inhibit growth of bacterial organisms. The laboratory had not established any IQCP (Individualized Quality Control Plan). This affected the survey review period of July 2017 - June 20, 2019. This is a repeat deficiency. The laboratory failed to implement corrective actions, according to the Plan of Corrections, submitted in response to the survey, conducted on June 6, 2017. The findings include: 1. A review of the QC records for fungal cultures revealed for the survey review period, July 2017 - June 20, 2019, the laboratory had retained only one label for the DTM media. The laboratory had retained the label for the DTM media, Lot #D11700216, which did not indicate an exact received date (top of sheet of paper indicated July of 2017), and failed to include documentation of a visual inspection. 2. At 1:00 PM on June 20, 2019, the surveyor inquired of the LD the procedure for fungal culture QC. The LD stated the laboratory staff were not documenting the visual inspections of the fungal media, although the nurses look at each box. The LD added that the staff were retaining the labels for the Uricult media. The surveyor reminded the laboratory director of this repeat failure and of the similar discussion on the previous survey in 2017. 3. A review of the Uricult QC records for July 2017 - June 20, 2019 revealed the laboratory retained the manufacturer's labels with the lot numbers of the media and expiration dates, as well as documentation of visual inspections. However, the laboratory failed to perform quality control verifications of the media to ensure the media was capable of supporting growth. 4. At 1:00 PM on June 20, 2019, the LD stated he had worked on developing an IQCP for two years, but had not succeeded. The LD further stated the task was not within his scope of knowledge. The LD provided an out-dated procedure from 2014, which included no risk assessments, quality assurance plan or established quality control plan (unacceptable for IQCP). The surveyor stated to the LD the laboratory staff had not always documented the received dates of the Uricult media. This was confirmed by the LD.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on a review of the Uricult and DTM (Dermatophyte Test Medium) Fungal Culture Quality Control (QC) records, a lack of documentation, and an interview with the Laboratory Director (LD), who also serves as the Technical Consultant (TC), the surveyor determined the LD failed to ensure the staff performed and documented visual inspections of the Acu-DTM media. The LD further failed to ensure the staff performed quality control of the Uricult [CLED (Cystine-Lactose Electrolyte Deficient /EMB(Eosin Methylene Blue)] media to verify its ability to support growth and select or inhibit growth of bacterial organisms. The laboratory had not established any IQCP (Individualized Quality Control Plan). This affected the survey review period of July 2017 - June 20, 2019. This is a repeat deficiency. The Laboratory Director failed to implement corrective actions, according to the Plan of Corrections, submitted in response to the survey, conducted on June 6, 2017. The findings include: 1. Refer to D6020 (also D5477).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the Uricult and DTM (Dermatophyte Test Medium) Fungal Culture Quality Control (QC) records, a lack of documentation, and an interview with the Laboratory Director (LD), who also serves as the Technical Consultant (TC), the surveyor determined the LD failed to ensure the staff performed and documented visual inspections of the Acu-DTM media. The LD further failed to ensure the staff performed quality control of the Uricult [CLED (Cystine-Lactose Electrolyte Deficient /EMB(Eosin Methylene Blue)] media to verify its ability to support growth and select or inhibit growth of bacterial organisms. The laboratory had not established any IQCP (Individualized Quality Control Plan). This affected the survey review period of July 2017 - June 20, 2019. This is a repeat deficiency. The Laboratory Director failed to implement corrective actions, according to the Plan of Corrections, submitted in response to the survey, conducted on June 6, 2017. The findings include: 1. Refer to D5477.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with the Laboratory Director, who also serves as the Technical Consultant, the surveyor determined the

	Technical Consultant failed to perform an annual competency assessment on Testing Personnel (TP) #8. This affected one of eleven personnel who performed moderate complexity testing. The findings include: 1. The Laboratory Director (Technical Consultant) listed eleven testing personnel on the Laboratory Personnel Report (CMS form #209). 2. A review of the personnel records revealed TP #8 had previously qualified (on the previous survey in 2017) as a personnel of moderate complexity testing was trained, prior to the current survey. 3. At 11:14 AM on June 20, 2019, the Laboratory Director stated all of the listed personnel perform non-waived testing. The surveyor inquired of a 2019 annual competency for TP #8, since documentation indicated the annual assessment in 2018 occurred in January. The Laboratory Director (also the Technical Consultant) reviewed the personnel's file and stated he must have missed the employee's annual competency for 2019.