Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0921240	07/03/2019
Name of Provider or Supplier	**Street Address, City, State**	
Grace Family Practice Clinic, Pc	1716 Parr Ave Ste D, Dyersburg, TN	

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
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the 2018 and 2019 proficiency testing (PT) records and interview with testing personnel number one, the laboratory failed to perform and document remedial action for the red blood count, hematocrit and automated differential lymphocyte unacceptable scores. The findings include: 1) Review of the 2018 and 2019 PT records revealed the following unacceptable sample scores with no remedial actions documented: 2018 event two sample number HD-08 for hematocrit; 2018 event three sample number HD-11 for red blood count and hematocrit; and, 2019 event one sample numbers HD-01, HD-02, HD-03, HD-04 and HD-05 for automated differential lymphocyte. 2) Interview on July 3, 2019 at 2:30 p.m. with testing personnel number one confirmed the unacceptable sample numbers were circled with no further remedial action documentation.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with testing personnel number one, the laboratory failed to have a procedure to include all six criteria for assessing personnel competency. The findings include: 1) Review of the laboratory procedure manual revealed the following six criteria were not included in the testing personnel competency procedure: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. 2) Interview on July 3, 2019 at 3:00 p.m. with testing personnel number one confirmed the testing personnel competency procedure did not include the six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS).
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the proficiency testing records and interview with testing personnel number one, the laboratory failed to verify the accuracy of the wet prep and potassium hydroxide (KOH) at least twice per year in 2017. The findings include: 1) Review of the 2017 proficiency testing records revealed the 2017 events one, two and three scored 50% each event for the wet prep and KOH analytes, with no further accuracy documented. 2) Interview on July 3, 2019 at 2:45 p.m. with testing personnel number one confirmed the remedial action for the wet prep and KOH failed scores did not include documentation to verify the accuracy in 2017.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in

	the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of Form Centers for Medicare and Medicaid Services (CMS)-209, patient number one final report, the laboratory procedure manual and interview with testing personnel number one, the laboratory failed to have a step-by-step performance of the Whiff procedure. The findings include: 1) Review of patient number one final report revealed on May 7, 2019 a negative Whiff was reported with the wet prep and KOH. 2) Review of the laboratory procedure manual revealed the wet prep and KOH procedures did not include a step-by-step performance of the Whiff procedure. 3) Interview on July 3, 2019 at 4:02 p.m. with testing personnel number one confirmed the laboratory procedure manual did not include a step-by-step procedure for the Whiff test.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory manuals, the complete blood count (CBC) instrument operator manual and interview with testing personnel number one, the current laboratory director failed to approve, sign and date all the laboratory manuals, including but not limited to, the CBC instrument operator's manual, in May 2019. The findings include: 1) Review of the Form CMS-209 revealed a new current laboratory director. 2) Review of the laboratory manuals and the CBC instrument operator manual revealed the current laboratory director did not approve, sign and date these procedures. 3) Interview on July 3, 2019 at 2:00 p.m. with testing personnel number one confirmed the current laboratory director began May 15, 2019 and has not approved, signed and dated the laboratory manuals and CBC instrument operator manual.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manuals available and interview with testing personnel number one, the laboratory director failed to ensure the quality assessment (QA) plan was available for review. The findings include: 1) Review of the available laboratory procedure manuals revealed no QA plan was available for

	review. The QA plan should include system processes for the following: preanalytic processes (assessing specimen handling problems); analytic problems (assessing equipment, instruments, reagents, storage conditions, instrument function checks, calibration reviews, corrective actions), and postanalytic (patient specific data). 2) Interview on July 3, 2019 at 3:45 p.m. with testing personnel number one confirmed the monthly QA checklist with instructions is the only QA plan available for review and that the no other QA plan was available for review.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: The laboratory technical consultant qualification documentation was not available. (Refer to D6034).
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Form Centers for Medicare and Medicaid Services (CMS) 209, review of the personnel records, interview with testing personnel number one and the office manager, the technical consultant qualification documentation was not available for review. The findings include: 1) Observation of the laboratory on July 3, 2019 at 1:53 p.m. revealed the Abbott Cell-Dyn 1800 instrument in use for patient complete blood count (CBC) testing and two microscopes in use for wet prep and potassium hydroxide (KOH) patient testing. 2) Review of the Form CMS-209 revealed the current laboratory director name is marked as the technical consultant. 3) Review of the technical consultant personnel records revealed no documentation for at least one year of laboratory clinical training or experience for the mycology (KOH), parasitology (wet prep) and hematology specialties. 4) Interview on July 3, 2019 at 2:15 p.m. with testing personnel number one confirmed the technical consultant performs wet prep and KOH patient testing, but there is no documentation of experience. The technical consultant does not perform patient CBC testing. 5) Interview on July 3, 2019 at 4:30 p.m. with the office manager confirmed the technical consultant began May 15, 2019 and that there is no documentation of the technical consultant qualification of one year of clinical experience for the technical consultant position.