Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0313471	07/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Rhea Clinic Pc	17310 Hwy 64, Somerville, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. 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 testing personnel performing the wet prep and urine microscopic results did not sign the attestation statement. The findings include: 1) Review of the 2018 events one, two, three, 2019 events one and two PT records revealed the testing personnel signatures on the PT attestation statement were not testing personnel that were performing the wet prep and microscopic results. 2) Interview on July 23, 2019 at 10:20 a.m. with testing personnel number one confirmed the providers perform the wet prep and urine microscopic examinations, but did not sign the PT attestation statements.
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 laboratory quality assessment (QA) procedure, the 2018 proficiency testing (PT) records, and interview with testing personnel number one, the laboratory failed to verify the accuracy of the urine microscopic analyte in 2018. The findings include: 1) Review of the QA procedure revealed no procedure for verifying

	the urine microscopic analyte accuracy twice a year. 2) Review of the 2018 PT records revealed no participation in 2018 events one and two, and a score of 50% for event three. 3) Interview on July 23, 2019, at 11:30 am with testing personnel number one confirmed the urine microscopic analyte did not receive scores in 2018 events one and two and a 50% score in event three. There is no verification of accuracy for the urine microscopic analyte in 2018.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the temperature logsheets and interview with the office manager, the laboratory failed to document the temperature of the refrigerator, in 2017, 2018 and 2019. The findings include: 1) Observation on July 23, 2019 at 10:05 a.m. of the laboratory revealed two refrigerators in use, number one labeled for the laboratory, number two labeled for the reference laboratory. The laboratory complete blood count (CBC) quality control (QC) samples were maintained in the number two refrigerator. 2) Review of the 2017, 2018 and 2019 temperature logsheets revealed refrigerator temperature documentation for one refrigerator. 3) Interview on July 23, 2019 at 11:50 a.m. with office manager confirmed the number two refrigerator belonged to the reference laboratory and that the laboratory stored the CBC QC samples in the number two refrigerator. The laboratory did not record the temperature of the number two reference laboratory refrigerator in 2017, 2018 and 2019.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the complete blood count (CBC) records and interview with testing personnel number one, the laboratory failed to establish, perform and document a maintenance and/or function check protocol, in 2019. The findings include: 1) Review of the CBC records revealed the mainteance and/or function check for the Abbot Cell Dyn Emerald was not established and documented beginning May 2019 to current survey date, July 23, 2019. 2) Interview on July 23, 2019, at 11:10 a. m. with testing personnel number one confirmed the maintenance logsheet for the

	Abbott Cell Dyn Emerald was not established for the maintenance and/or function checks documentation, beginning May 2019. There is no documentation of the maintenance and/or function checks.
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: The laboratory director failed review, approve, sign and date the verification of performance specifications (Refer to D6013); failed to ensure the PT results were returned to the PT agency (Refer to D6017); failed to perform and document proficiency testing corrective action for unacceptable scores (Refer to D6019); failed to ensure the complete blood count quality control program was maintained (Refer to 6020); failed to assure the quality assessment was maintained (Refer to 6021); failed to ensure the complete blood count instrument was functioning properly (Refer to 6025); and, failed to ensure the complete blood count operator's manual was available for testing personnel (Refer to D6031).
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 observation of the laboratory, review of the verification of performance specifications records and interview with testing personnel number one, the laboratory director failed to review, approve, sign and date the verification of performance specifications for the Abbott Cell Dyn Emerald, in 2019. The findings include: 1) Observation on July 23, 2019 at 10:00 a.m. of the laboratory revealed the Abbott Cell Dyn Emerald in use for patient testing. 2) Review of the verification of performance specifications records for the Abbott Cell Dyn Emerald revealed no review by the laboratory director. No linearity was established for white blood count (WBC), red blood count, hemoglobin, hematocrit, platelet count and the automated WBC differential. 3) Interview on July 23, 2019 at 10:15 a.m. with testing personnel number one confirmed the verification of performance specifications were not approved by the laboratory director.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the 2018 proficiency testing (PT) records and interview with testing personnel number one, the laboratory director failed to ensure the urine microscopy results were returned to the PT agency in 2018 events one and two. The findings include: 1) Observation on July 23, 2019 at 10:00 a. m. of the laboratory revealed a microscope in use for patient urine microscopic analyte testing. 2) Review of the 2018 PT records revealed that in events one and two, no results for the urine microscopic analyte were sent to the PT agency. 3) Interview on July 23, 2019 at 10:40 a.m. with testing personnel number one confirmed the laboratory did not participate in the 2018 events one and two for the urine microscopic analyte, with patient testing reported.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. 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 director failed to perform and document corrective action for the unacceptable scores in 2018 and 2019. The findings include: 1) Review of the 2018 and 2019 PT records revealed the following unacceptable scores with no corrective action performed and documented: 2018 event three urine sediment number US-6 unacceptable 2019 event one urine sediment number US -1 unacceptable 2019 event two urine sediment number US-3 unacceptable 2018 event two hemoglobin number SYX-8 unacceptable 2019 event two hemoglobin numbers SYX-6,7,8,9,10 unacceptable 2019 event two mixedW /MCR numbers SYX-6,7,8,9,10 unacceptable 2019 event two Neut W/LCR numbers SYX-6, 7, 8,9,10 unacceptable 2018 event three wet mount number PPM-13 unacceptable 2) Interview on July 23, 2019 at 10:45 a.m. with testing personnel number one confirmed corrective action for the unacceptable PT scores was not performed and documented.
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 review of the complete blood count (CBC) quality control (QC) records, the manufacturer's assay value and mean range package insert, review of the CBC instrument history report and interview with testing personnel number one, the laboratory director failed to ensure the CBC QC program was maintained to assure the quality of the CBC patient results, in 2019. The findings include: 1) Review of the July 2019 CBC QC records and the manufacturer's assay value and mean range package insert revealed lot number 9182 in use for low, normal and high QC beginning July 3, 2019. The manufacturer's expected values were not entered correctly for the following analytes: low control: mid-range auto diff %; red blood cells (rbc); hemoglobin (hgb); hematocrit (hct); and platelet (plt); normal control: white blood count (wbc); lym absolute, gran absolute, lym auto diff %; rbc, hgb, hct, and plt; high control: mid-range absolute; lym auto diff %; mid-range auto diff %, rbc, hgb, hct and plt. 2) Review of the CBC instrument history report revealed patient testing beginning July 3, 2019 to current date, July 23, 2019. 3) Interview on July 23, 2019 at 12:10 p.m. with testing personnel number one confirmed the new lot number 9182 samples were in use beginning July 3, 2019. The new lot number 9182 acceptable limits were not entered into the CBC instrument. The laboratory director did not review the new lot values for accuracy.
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 quality assessment (QA) plan, review of the CBC instrument records and quality assessment (QA) records and interview with testing personnel number one, the laboratory director failed to assure the quality assessment was maintained, in 2018 and 2019. The findings include: 1) Review of the QA plan revealed, "The results of the Control runs are reviewed by technical consultant. The KX-21N generates a monthly Quality Control record. These reports and records are kept for (2) two years and are reviewed by the Director and/or the Technical Consultant." There is a "Quality Assurance Checklist" and a QA Compliance Laboratory Checklist". 2) Review of the CBC instrument records and the QA records revealed no review documentation by the laboratory director from 2018 to 2019. The Quality Assurance Checklist and the QA Compliance Laboratory Checklist were not performed and documented in 2018 and 2019. The manufacturer's package insert with each new lot number containing the acceptable limits were not maintained in 2018 and 2019. 3) Interview on July 23, 2019 at 12:30 p.m. with testing personnel number one confirmed the laboratory director did not review the CBC QC records, the QA checklist and QA compliance laboratory checklist were not used, in 2018 and 2019.

D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on review of the July 2019 complete blood count (CBC) quality control (QC) records, the CBC instrument history report and interview with testing personnel number one, the laboratory director failed to ensure the CBC instrument was functioning properly prior to reporting patient CBC test results on July 1 and 2, 2019. The findings include: 1) Review of the July 2019 CBC QC records revealed no CBC QC was performed for levels one, two and three on July 1 and 2, 2019. 2) Review of the CBC instrument history report revealed a total of 28 patient CBC test reports were performed and reported on July 1 and 2, 2019. 3) Interview on July 23, 2019 at 11:50 a.m. with testing personnel number one confirmed the CBC QC was not performed on July 1 and 2, 2019, with patient test results reported. The laboratory director did not ensure the CBC instrument was functioning properly prior to reporting patient results.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manuals and interview with testing personnel number one, the laboratory director failed to ensure the Abbott Cell Dyn Emerald Operator's Manual was available to all testing personnel in 2019. The finding include: 1) Observation on July 23, 2019, of the laboratory revealed the Abbott Cell Dyn Emerald (serial number 7752) in use for patient testing. 2) Review of the laboratory procedure manuals revealed the Abbott Cell Dyn Emerald Operator's Manual was an unopened compact disk. 3) Interview on July 23, 2019 at 10:45 a.m. with testing personnel number one confirmed the unopened compact disk was the Abbott Cell Dyn Emerald Operator's Manual, but was unsure of how to access the electronic information.