Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2017717	12/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Chamnong Family Medicine	8300 Crossland Loop, Montgomery, 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
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 API (American Proficiency Institute) proficiency testing (PT) records and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to retain the PT reporting forms for three out of six surveys, and failed to ensure the Laboratory Director signed attestation statements for two of six 2016-2018 surveys reviewed. The findings include: 1. A review of the API PT records revealed the laboratory had begun entering their results electronically via the API website for the 2016-Event #3 survey, but had failed to print copies of the submitted results for the first three Hematology surveys, as follows: 2016-Event #3, 2017-Events #1 and #2. 2. A review of the attestation statements revealed TP #1 had signed as the Laboratory Director for the 2016-Event #3 and the 2017-Event #2 Hematology surveys. 3. During an interview and review of the records on 12/11/2018 at 11:25 AM, the surveyor asked if the Laboratory Director had implemented a policy delegating the authority to sign the PT. [The surveyor also explained this can only be delegated to an individual who met the qualification of a Technical Consultant.] TP #1 stated the Laboratory Director had not delegated this authority. The surveyor then

	asked if the laboratory had retained PT reporting forms for the above three surveys; TP #1 answered, no, she did not begin printing the submitted results until the 2017-Event #3 survey. Thus the above noted findings were confirmed. 4. This is a repeat deficiency.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on a review of patient results reports and an interview with Testing Personnel (TP) #1, the laboratory failed to implement a mechanism to ensure complete patient CBC (Complete Blood Count) reports were retained for at least two years. The findings include: 1. On 12/11/2018 at 1:20 PM, TP #1 was asked about the post-analytical process in the facility, how results were retained and whether patients can obtain copies of their CBC results for themselves or a consulting physician. TP #1 explained the testing personnel entered the patient identification number in the analyzer when they ran the CBC. The instrument printout was then given to the Laboratory Director (the patient's physician) for review. The Director then manually entered some of the data (the White Blood Cell, Hemoglobin, Platelet count and abnormal results) in the SequelMed electronic medical record. 2. As the interview continued TP #1 explained the laboratory also printed the Medonic cumulative patient log with all the data from CBC's run each month; individual CBC's could also be reprinted for the analyzer including the MRN with the patient's name written on the reports. The surveyor then asked if the Medonic retained the CBC for individual patients for two years, and requested the 1/4/2017 report for a specific patient MRN. 3. The interview resumed on 12/11/2018 at 1:45 PM, when TP #1 returned with a CBC report for the specified patient, however the report was dated 11/14/2018 (not 1/4 /2017, as requested). TP #1 explained the Medonic only saved the most recent results for each MRN, and could not print the previous CBC's. TP #1 confirmed the laboratory did not have a mechanism of retaining records for all of their patients for a two-year period as required by CLIA.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on reviews of the Hematology quality control records, and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to implement a mechanism to monitor quality control (QC) shifts and trends over time for twelve month from November 2017 thru September 2018. The findings include: 1. A review of the 2016-2018 Medonic Hematology analyzer QC records revealed from November 2017 thru September 2018 only the daily QC instrument printouts had been printed and retained, plus sheets calculating the means and standard deviations for the analytes on each QC level. The QC statistics were signed by the previous Technical Consultant. 2. During the exit summation interview on 12/11/2018 at 1:55 PM, Testing Personnel #1 was asked if the laboratory had implemented another mechanism to routinely monitor control shifts and trends, such as submission of the QC results to an Interlaboratory Quality Assurance Program (eCQAP), or printing cumulative Levy-Jennings charts for the above twelve months. Testing Personnel #1 explained they had submitted all their statistical QC results to the eCQAP program, however the company had stopped mailing the reports in late 2017. She had the option of printing the electronic reports, however she had not. The previous Technical Consultant had never explained they needed this data to demonstrate the long-term monitoring of the QC, and Testing Personnel #1 had not realized the significance of the reports. Thus the above noted findings were confirmed. .
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a lack of documentation in the personnel file for Testing Personnel (TP) #4, #5 and #8, and interviews with TP #1 and the Laboratory Director, the Director failed to ensure training for three of eight testing personnel was performed and documented before patient testing began. The finding include: 1. A review of the employee files for testing personnel performing and resulting CBC's (Complete Blood Counts) on patient specimens revealed no documentation of training for moderate-complexity testing performed on the Medonic M Series Hematology analyzer for the "new" personnel as follows: A) TP #4-Hired in September 2017 B) TP #5-Hired 10/31/2016, and C) TP #8-Hired March 2017 2. During an interview on 12/11/2018 at 10:10 AM, the surveyor asked TP #1 about the training on the Medonic Hematology analyzer for the newer testing personnel. TP #1 stated the Laboratory Director watched the testing personnel perform the steps of running a CBC. When asked if this "training" was documented, TP #1 reviewed the employee files with the surveyor, and confirmed she did not see any Medonic training documented. 3. During the exit summation on 12/11 /2018 at approximately 1:55 PM, TP #1 (with the Laboratory Director present) showed the surveyor the "Medonic Training Checklist". All of the older personnel had documentation of training during the installation of the analyzer, however the Laboratory Director had failed to ensure the newer testing personnel had received and

	documented the same training. Thus the above noted findings were confirmed. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor