Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0313772	(X3) Date Survey Completed 08/08/2018
Name of Provider or Supplier Church Health Center Of Memphis, Inc	**Street Address, City, State** 1350 Concourse Ave Ste 142, Floors 1 & 2, Memphis, 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
D0000	A revisit survey was conducted on Church health Center of Memphis, INC. for all previous deficiencies cited on August 8, 2018. All deficiencies have been corrected, and no new noncompliance was found. The facility is in compliance with all regulations surveyed.
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: Review of the laboratory's proficiency testing attestation statements for 2016 event three, 2017 events one, two, and three, and 2018 event one and two, the laboratory failed to rotate proficiency testing among personnel who routinely perform patient testing in 2016, 2017, and 2018. The findings include: 1. Review of the attestation statements for the Family Medicine upstairs laboratory revealed the signature of testing personnel number two for 2016 event three, 2017 events one, two, and three, and 2018 events one and two (five of five events). 2. Review of the attestation statements for the Central downstairs laboratory revealed the signature of testing personnel number one for 2016 event three, 2017 events one, two, and three, and 2018 event one (four of five events). 3. Interview with the technical consultant on August 8, 2018 at 11:00 am confirmed the laboratory failed to rotate proficiency testing in 2016, 2017, and 2018.
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 observation of the laboratory, review of the laboratory's proficiency testing records, the provider competency assessment records used for verifying accuracy of urine microscopy, wet prep and potassium hydroxide (KOH) procedures, the Centers for Medicare and Medicaid Services form 2567 (CMS 2567) from the recertification survey conducted on 08.08.2016, interview with testing personnel number one and the technical consultant, the laboratory failed to verify the accuracy of urine sediment identification, wet prep and KOH procedures in 2018. 1. Observation of the first floor Central Laboratory on 8.8.2018 at 9:00 am and the second floor Family Practice laboratory on 08.08.2018 at 9:30 am revealed microscopes in the testing areas in use for patient testing. 2. Review of the laboratory's proficiency testing records revealed the laboratory was not enrolled in proficiency testing for urine sediment identification, wet prep, or KOH testing. 3. Review of the provider competency assessment records used for verifying accuracy of the urine microscopy, wet prep and KOH procedures revealed no documents were available for 2018. 4. Review of the CMS 2567 from the recertification survey conducted on 08.08.2016 revealed the same deficiency was cited. 5. Interview with testing personnel number one on 8.8.2018 at 9:00 am confirmed the microscopes are in use for patient testing and the laboratory performs testing for urine sediment identificaton, wet prep, and KOH. 6. Interview with the technical consultant on August 8, 2018 at 11:00 am confirmed the laboratory uses provider competency assessments for verification of the accuracy of urine sediment identification, wet prep and KOH patient testing, had not verified the accuracy of urine microscopy, wet prep and KOH procedures twice a year in 2018, and this was a repeat deficiency from the recertification survey conducted on 08.08.2016.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, the laboratory's quality assessment plan, quality assessment (QA) activity records, the quality control records for the complete blood count instrument, and interview with the technical consultant, the laboratory failed to have a clear quality assessment plan and did not follow the available plan available in 2016, 2017, and 2018. The findings include: 1. Review of the laboratory's procedure manual revealed a policy titled "Church Health Center of Memphis Quality Assessment Program," signed by the laboratory director on 5.4.2016. 2. Review of the laboratory's quality assessment plan revealed the following statements: "Each month, via the QA checklist, we monitor the following aspects of laboratory testing." "For test results that produce a quantitative result, Levy-Jennings charts are routinely reviewed by the Technical Consultant and/or Director to identify shifts, trends and outliers. 3. Review of the records documenting QA activities revealed the following dates when quality assessment was performed: 12.5.16, 12-13-17, 8.2.18, and review of the quality control records for the complete blood count

	instruments revealed no Levy-Jennings charts were present for 2016, 2017, and 2018 and there was no documented monthly review of quality control. 4. Interview with the technical consultant on 8.8.2018 at 12:30 pm confirmed there was no clear quality assessment plan in use in 2016, 2017 and 2018 and the laboratory did not follow the plan available in 2016, 2017, and 2018.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with testing personnel number one, the laboratory failed to label the saline reagent with open date and expiration date in 2018. The findings include: 1. Observation of the first floor laboratory on August 8, 2018 at 9:00 am revealed a bottle labeled "saline" in use for patient wet prep testing with no open date or expiration date. 2. Interview with testing personnel number one on August 8, 2018 at 9:15 am confirmed the bottle labeled "saline" was in use for patient testing for wet prep and was not labeled with open date or expiration date.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the package inserts for complete blood count (CBC) quality control (QC) lot numbers 067700, 077700, 087700, the daily CBC quality control records performed on 12-08-2016, patient number eleven test report, the Centers for Medicare and Medicaid Services form 2567 (CMS 2567)and interview with the technical consultant, the laboratory failed to ensure controls were not used past their expiration date in 2016. The findings include: 1. Review of the package inserts for CBC quality control lot numbers 067700, 077700, 087700 revealed an expiration date of 12-06-2016 for all lots. 2. Review of the daily CBC quality control records performed on 12-08-2016 revealed the use of lot numbers 067700, 077700, and 087700. 3. Review of patient number eleven test report revealed patient testing performed for CBC on 12-08-2018. 4. Review of the CMS 2567 from the recertification survey performed on August 8, 2016 revealed the same deficiency for using CBC controls past their expiration date. 4. Interview with the technical consultant on August 8, 2018 at 3pm confirmed the laboratory used expired quality control material on December 8, 2016 with patient testing performed, and confirmed that this was a repeat deficiency from the previous survey.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)

	(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation of the first floor Central Laboratory and the second floor Family Practice laboratories, laboratory records, the Centers for Medicare and Medicaid Services form 2567 (CMS 2567) and interview with the technical consultant, the laboratory failed to compare results between the two complete blood instruments twice a year in 2017 and 2018. The findings include: 1. Observation of the first floor Central Laboratory on August 8, 2018 at 9:00 am revealed a Beckman Coulter AcT Diff instrument in use for patient testing for complete blood count. 2. Observation of the second floor Family Practice Laboratory on August 8, 2018 at 9:30 am revealed a second Beckman Coulter AcT Diff instrument in use for patient testing for complete blood count. 3. Review of laboratory records revealed that no records were available comparing the two instruments twice a year in 2017, and 2018. 4. Review of the CMS 2567 from the previous survey conducted on August 8, 2016 revealed the same deficiency was cited. 5. Interview with the technical consultant on August 8, 2018 at 12:30 pm confirmed the results from the two instruments used for performing patient CBC testing had not been compared in 2017 and 2018 and this was a repeat deficiency from the prior recertification survey conducted on 8.08.2016.
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 review of the Centers for Medicare and Medicaid Services form 209 (CMS 209), testing personnel records, and interviews with the technical consultant and director of medical operations, the laboratory director failed to ensure testing personnel received training and demonstrated accurate test performance prior to patient testing in 2016, 2017, and 2018. The findings include: 1. Review of the CMS 209 form from the previous survey with comparison to the current CMS 209 revealed the following as new testing personnel since the last survey: numbers 16, 17, 18, 19, 22 and 23. 2. Review of testing personnel records revealed no initial training or documents that showed demonstration of accurate test performance prior to patient testing for testing personnel numbers 16, 17, 18, 19, 22 and 23. 3. Interview with the director of medical operations on August 8, 2018 revealed the following dates of hire: #16 = 08.11.16, #17=2.28.18, #18=8.24.16, #19 = 8.21.17, #22 = 9.1.16, #23 = 11.13.17. 3. Interview with the technical consultant on August 8, 2018 at 11:30 am

	confirmed that testing personnel numbers 16, 17, 18, 19, 22 and 23 did not received training or demonstrated accurate test performance prior to patient testing in 2016, 2017, and 2018.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services form 209 (CMS 209), testing personnel records, and interviews with the director of medical operations and the technical consultant, the technical consultant failed to evaluate the competency of testing personnel numbers 19 and 23 in 2017 and 2018. The findings include: 1. Review of the CMS form 209 revealed the names of testing personnel numbers 19 and 23. 2. Review of testing personnel records revealed no competency assessment documents were available for testing personnel numbers 19, and 23. 3. Interview with the director of medical operations on August 8, 2018 revealed the following dates of hire: #19 = 8.21.17, #23 = 11.13.17. 4. Interview with the technical consultant on August 8, 2018 at 11:30 am confirmed that testing personnel numbers 19 and 23 perform patient testing, there was no documented competency assessments present for testing personnel numbers 19 and 23 and the technical consultant failed to evaluate the competency of all testing personnel in 2017 and 2018.
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 review of testing personnel competency assessment records and interview with the technical consultant, the technical consultant failed to perform annual competency assessment for testing personnel numbers 16, 18, and 22. The findings include: 1. Review of testing personnel competency assessment records revealed the last competency assessment performed for testing personnel numbers 16, 18, and 22 was January 2017. 2. Interview with the technical consultant on August 8, 2018 at 11: 00 am confirmed the technical consultant failed to perform annual competency assessment for testing personnel numbers 16, 18, and 22 in 2018.