Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0318918	07/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Hattiesburg Clinic Laboratory	421 S 28th Ave Ste 300, Hattiesburg, MS	

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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records available on 07/22/22, there was no documented verification or review of scores for analytes that received ungraded or "no consensus" PT scores. Findings include: No review or verification was documented for analytes with the following PT scores: 1) Ungraded results on Chemistry Miscellaneous Event 1 in 2022: a. Cystatin (2 samples) 2) Ungraded (no consensus) results on Immunology/Immunohematology Event 1 in 2022: a. CCP (1 sample) 3) Ungraded results on Hematology/Coagulation Event 1 in 2022: a. Sperm Classification (3 samples) b. Sperm Morphology (2 samples) c. Educational Blood Cell Identification--automated (6 samples) d. Educational Blood Cell Identification--manual (5 samples) e. Educational Platelet Estimate (1 sample) 4) Ungraded results on Hematology/Coagulation Event 3 in 2021 a. Sperm Classification (6 samples) b. Sperm Morphology (2 samples) 5) Ungraded results on Hematology/Coagulation Event 2 in 2021 a. Blood Cell Identification (1 sample) b. Educational Blood Cell Identification--manual (5 samples) c. Educational Platelet Estimate (1 sample) 6) Ungraded results on Hematology/Coagulation Event 1 in 2021 a. Sperm Classification (2 samples) b. Sperm Morphology (1 sample) c. Sperm Count (1 sample) d. Educational Blood Cell Identification-auto (6 samples) e. Educational Platelet Estimate (1 sample) f. Educational Blood Cell Identification-manual (5 samples) g. Urine crystal (1 sample)

D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records available on 07/22/2022, there was no documented review of all unacceptable PT scores and the corrective action taken. Findings include: No record review or corrective action was documented for the following Proficiency Testing scores: (1) Unacceptable results on Chemistry Core Event 2 in 2022: a. Free T3 - 1 sample - 80% b. Estradiol - 1 sample - 80% c. Testosterone - 1 sample - 80% 2) Unacceptable results on Hematology/Coagulation Event 1 in 2022: a. Sperm Classification (1 sample) 3) Unacceptable results on Hematology/Coagulation Event 1 in 2021 a. Urine crystal (1 sample)
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of verification of performance specifications for the three Abbott Alinity C chemistry analyzers put in use on 6/29/22, review of manufacturer's instructions for use of the reagents used with the Alinity C analyzers, the Food and Drug Administration (FDA) categorization database, and confirmation by the general supervisor, the laboratory failed to establish performance specifications for the Sekisui Diagnostics Albumin Assay and the Kamiya Biomedical Company Cystatin C Assay in use on the Abbott Alinity C chemistry analyzers since 6/29/22 and in use on two Abbott Architect Plus C16000 analyzers since the last survey on 11/18/20 through 6/27/22. The patient test count for the Sekisui Diagnostics Albumin assay for 6/29/22 through 7/22/22 was 939. The patient test count for the Kamiya Biomedical Company Cystatin C Assay for 4/1/22 through 7/22/22 was 7. Findings include: Review of verification of performance specifications for the three Abbott Alinity C chemistry analyzers and manufacturer's instructions for use of the reagents used with the Alinity C analyzers revealed the Sekisui Diagnostics Albumin Assay and the Kamiya Biomedical Company Cystatin C Assay were put in use for patient testing on 6/29/22. The general supervisor confirmed the Sekisui Diagnostics Albumin Assay and the Kamiya Biomedical Company Cystatin C Assay were in use on the two Abbott Architect Plus C16000 analyzers since the last survey on 11/18/20 through 6/27/22, when the Architect Plus C16000 analyzers were taken out of service. Review of the FDA categorization database revealed these two assays have not been classified for use on the Abbott Alinity C chemistry analyzer or the Abbott Architect Plus C16000

	analyzer. Therefore, these assays are considered high-complexity tests on these analyzers, requiring establishment of performance specifications on the Alinity C chemistry analyzers and the Architect Plus C16000 analyzers. There was no documentation available for review on 7/22/22 of the establishment of performance specifications for the Sekisui Diagnostics Albumin Assay or the Kamiya Biomedical Company Cystatin C Assay. The general supervisor confirmed the establishment of performance specifications had not been performed for these two assays.