Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0462715	02/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Baton Rouge Urology Group	7777 Hennessy Blvd Suite 2004, Baton Rouge, LA	

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 Recertification survey was performed on February 16, 2022 at Baton Rouge Urology Center, CLIA ID # 19D0462715. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(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 laboratory policy, proficiency testing records and interview with personnel, the laboratory failed to document remedial action for unacceptable Chemistry proficiency testing scores. Findings: 1. Review of the laboratory's "Proficiency Testing Policy" revealed "Any result that fails to meet the expected and /or acceptable criteria initiates a corrective action. Each event requires its own set of corrective action steps, which include: * Review of Calibration (where applicable) and Quality Control results for the date of analysis * Consider reagent issues (where applicable) * Consider instrument service (where applicable) * Review of all patient results for that particular day * All relative patient charts for that day must be pulled and the physician consulted regarding patient results for specific test(s) on that day, and the potential effect for each particular patient. Patients may be notified and/or retested * Any and all actions performed in response to these issues must be documented 2. Review of laboratory's American Academy of Family Physicians

	(AAFP) proficiency testing (PT) records from 2020 and 2021 revealed the following unacceptable results: a) AAFP PT 2020-A: sample CH-1N Albumin (ALB), score 80% b) AAFP PT 2020-A: sample CH-1N Total Protein (TP, score 80% c) AAFP PT 2021-A: sample CH-2N Albumin (ALB), score 80% 3. Further review of the laboratory's proficiency testing (PT) records for 2020 and 2021 revealed the laboratory did not have any documentation of corrective action, investigation or remedial action for the unacceptable scores. 4. In interview on February 16, 2022 at 3: 01 pm, Personnel 2 stated that she was unaware corrective action was required for PT scores of 80%. Personnel 2 confirmed the identified samples did not have documentation of corrective action or investigation.
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 laboratory policy, proficiency testing records and interview with personnel, the laboratory failed to document remedial actions for unacceptable Hematology scores. Findings: 1. Review of the laboratory's "Proficiency Testing Policy" revealed "Any result that fails to meet the expected and/or acceptable criteria initiates a corrective action. Each event requires its own set of corrective action steps, which include: * Review of Calibration (where applicable) and Quality Control results for the date of analysis * Consider reagent issues (where applicable) * Consider instrument service (where applicable) * Review of all patient results for that particular day * All relative patient charts for that day must be pulled and the physician consulted regarding patient results for specific test(s) on that day, and the potential effect for each particular patient. Patients may be notified and/or retested * Any and all actions performed in response to these issues must be documented 2. Review of laboratory's American Academy of Family Physicians (AAFP) proficiency testing (PT) records from 2020 and 2021 revealed the following unacceptable results: a) AAFP PT 2020-B: sample HD-7 Red Blood Cells (RBC), score 80% b) AAFP PT 2020-B: sample HD-7 Hematocrit (HCT), score 80% c) AAFP PT 2021-B: sample HD-7 White Blood Cells (WBC), score 80% d) AAFP PT 2021-B: sample HD-7 Red Blood Cells (RBC), score 80% e) AAFP PT 2021-B: sample HD-7 Hematocrit (HCT), score 80% 3. Further review of the laboratory's proficiency testing (PT) records for 2020 and 2021 revealed the laboratory did not have any documentation of corrective action, investigation or remedial action for the unacceptable scores. 4. In interview on February 16, 2022 at 3:01 pm, Personnel 2 stated that she was unaware corrective action was required for PT scores of 80%. Personnel 2 confirmed the identified samples did not have documentation of corrective action or investigation.
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 direct observation by surveyor and interview with personnel, the laboratory failed to ensure supplies did not exceed their expiration date. Findings: 1. Direct observation by surveyor during the laboratory tour on February 16, 2022 at 1:00 pm revealed the following expired supplies: a) BD vacutainer red serum tubes: Lot 0121033, Expiration 08/31/2021, Quantity: seven (7) 2. In interview on February 16, 2022 at 1:00 pm, Personnel 2 confirmed the identified supplies were expired.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation during laboratory tour, review of laboratory records and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417.
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 laboratory policy, proficiency testing records and interview with personnel, the Laboratory Director failed to ensure the laboratory performed corrective actions for unacceptable proficiency testing results. Findings: 1. The laboratory failed to document remedial action for unacceptable Chemistry proficiency testing scores. Refer to D2094. 2. The laboratory failed to document remedial actions for unacceptable Hematology testing scores. Refer to D2128.