

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0665653	(X3) Date Survey Completed 11/29/2021
Name of Provider or Supplier Baton Rouge Clinic - Family Clinic Of Opelousas	Street Address, City, State 3921 I-49 S Service Road, Opelousas, 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 at The Family Clinic, CLIA ID # 19D0665653, on November 29, 2021. The Family Clinic was found not in compliance with the following CONDITION LEVEL DEFICIENCIES : 42 CFR 493.1421 CONDITION : Laboratories Performing Moderate Complexity Testing; Testing Personnel 42 CFR 493.1403 CONDITION : Laboratories Performing Moderate Complexity Testing; Laboratory Director 42 CFR 493.1409 CONDITION : Laboratories Performing Moderate Complexity Testing; Technical Consultant
D2128	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and the American Proficiency Institute (API) proficiency testing records as well as 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 "All failures must be investigated" and "Documentation of the PT report review and what remedial/corrective actions will be taken for all unsatisfactory results is essential". 2. Review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed the laboratory received unacceptable results for the following two (2) of five (5) API events reviewed: a) 2021 Hematology /Coagulation 1st event: Score for Platelet Count - 80% b) 2021 Hematology</p>

/Coagulation 2nd event: Score for Urine Sediment - 50% c) 2021 Hematology
/Coagulation 2nd event: Score for Blood Cell Identification - 80% 3. Further review of the laboratory's API proficiency testing records revealed no documentation of corrective action, investigation, or remedial action for these unacceptable scores. 4. In interview on November 29, 2021 at 4:30 pm, the Technical Consultant stated she was thought that remedial action was only performed if the event score was below 80%. The Technical Consultant confirmed that no remedial action was performed for the above identified scores.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policy and procedure manual, personnel records and interview with personnel, the laboratory failed to follow their established competency policy for three (3) of seven (7) testing personnel reviewed. Findings: 1. Review of the laboratory's "Staff Competency" policy revealed "Staff competency will be determined by utilizing the following procedures: 1) Direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing. 2) Monitoring the recording and reporting of test results. 3) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. 4) Direct observation of performance of instrument maintenance and function checks. 5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 6) Assessment of problem solving skills". 2. Further review of the laboratory's "Staff Competency" policy revealed "Competency is assessed at 90 days, 6 months and 12 months post initial training and then annually thereafter". 3. In interview on November 29, 2021 at 4:27 pm, the Technical Consultant stated three (3) of the testing personnel listed on the CMS 209 (Laboratory Personnel Form) performs Provider-Performed Microscopy (PPM) procedures only. 4. Review of the laboratory's personnel records from 2020 and 2021 revealed the laboratory did not perform competency assessments for the following three (3) of seven (7) testing personnel reviewed: a) Personnel 7 b) Personnel 8 c) Personnel 9 5. In further interview on November 29, 2021 at 4:27 pm, the Technical Consultant stated that she was unaware that testing personnel performing PPM procedures required competency assessments. The Technical Consultant confirmed the above identified testing personnel did not have a competency assessments performed for 2020 and 2021.

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:

Based on direct observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure the laboratory employed testing personnel that met the state licensure requirements. Refer to D6028.

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 proficiency testing records and interview with personnel, the Laboratory Director failed to ensure the laboratory performed corrective actions for unacceptable proficiency testing results. Refer to D2128.

D6028

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(10)

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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:
Based on review of laboratory personnel records and interview with laboratory personnel, the Laboratory Director failed to ensure the laboratory employed testing personnel that met the state licensure requirements. Refer to D6064.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

	<p>This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.</p>
<p>D6046</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Technical Consultant failed to evaluate the competency of three (3) of seven (7) testing personnel performing Provider-Performed Microscopy (PPM) procedures for 2020 and 2021. Refer to D5209.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of personnel records and interview with personnel, the laboratory failed to provide documentation to ensure testing personnel met licensure requirements. Refer to D6064.</p>
<p>D6064</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a)</p> <p>Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS 209 (Laboratory Personnel Report), personnel records, Louisiana State Board of Medical Examiners (LSBME) online verification, and interview with personnel, the laboratory failed to ensure testing personnel met the state of Louisiana licensure requirement for the following one (1) of seven (7) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) revealed that Personnel 3 performs moderate complexity testing for Hematology and Chemistry. 2. Review of personnel records for Personnel 3 revealed documentation of a High School diploma for education; however, the personnel records for Personnel 3 did not include a state license covering moderate complexity testing issued by Louisiana State Board of Medical Examiners (LSBME). 3. Review of the LSBME online verification revealed that there is not a laboratory personnel license for Personnel 3. 4. In interview on November 29, 2021 at 4:27 pm, the</p>

Technical Consultant stated she was unaware that Personnel 3 did not have a Louisiana licensure in the personnel records. The Technical Consultant confirmed Personnel 3 did not have a Louisiana State laboratory license to perform moderate complexity testing.