

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0648630	(X3) Date Survey Completed 10/11/2022
Name of Provider or Supplier Crittenden Community Hospital	Street Address, City, State 520 West Gum, Marion, KY	
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	Based on a proficiency testing desk review performed on October 11, 2022 the laboratory was found to be out of compliance for the following conditions: D2016 - SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) D6000 - MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 D6076 - LABORATORY DIRECTOR CFR(s): 493.1441
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of CMS database proficiency performance report (155D) and American Proficiency Institute (API) performance evaluation for 2021 and 2022 the laboratory failed to attain satisfactory performance scores for 2 out of 3 consecutive</p>

testing events resulting in unsatisfactory participation for the analytes of infectious mononucleosis (Inf mono), rheumatoid factor (RF), antibody detection, ABO group, D (Rho), and compatibility testing. (See D2084, D2162, D2163, D2172, and D2181

D2084

GENERAL IMMUNOLOGY

CFR(s): 493.837(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on record review of CMS 155D and API performance evaluation for 2021 and 2022 showed that the laboratory failed to attain satisfactory scores for 2 out of 3 testing events resulting in unsuccessful performance for the analytes of Infectious mononucleosis and Rheumatoid Factor for 2021 3rd event and 2022 2nd event.

Findings: 1) A review of 155D showed 2021 Event 3 score of 0% Inf mono and 0% RF, 2022 Event 2 score of 0% Inf mono and 0% RF 2) A review of API showed 2021 Event 3 score of 0% Inf mono and 0% RF, 2022 Event 2 score of 0% Inf mono and 0% RF

D2162

ABO GROUP AND D(RHO) TYPING

CFR(s): 493.859(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on record review of CMS 155D and API performance evaluation for 2021 and 2022 showed that the laboratory failed to attain satisfactory scores for 2 out of 3 testing events resulting in unsuccessful performance for ABO group and D typing for 2021 3rd event and 2022 2nd event. Findings: 1) A review of 155D showed 2021 Event 3 score of 0% ABO and 0% D, 2022 Event 2 score of 0% ABO and 0% D 2) A review of API showed 2021 Event 3 score of 0% ABO and 0% D, 2022 Event 2 score of 0% ABO and 0% D

D2163

ABO GROUP AND D(RHO) TYPING

CFR(s): 493.859(g)

Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on record review of CMS 155D and API performance evaluation for 2021 and 2022 showed that the laboratory failed to achieve an overall score of satisfactory for 2 out of 3 testing events resulting in unsuccessful performance for ABO/RHO for 2021

	<p>3rd event and 2022 2nd event. Findings: 1) A review of 155D showed 2021 Event 3 score of 0% ABO/RHO, 2022 Event 2 score of 0% ABO/RHO 2) A review of API showed 2021 Event 3 score of 0% ABO/RHO, 2022 Event 2 score of 0% ABO/RHO</p>
D2172	<p>UNEXPECTED ANTIBODY DETECTION CFR(s): 493.861(e)</p> <p>Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review of CMS 155D and API performance evaluation for 2021 and 2022 showed that the laboratory failed to achieve an overall score of satisfactory for 2 out of 3 testing events resulting in unsuccessful performance for antibody detection for 2021 3rd event and 2022 2nd event. Findings: 1) A review of 155D showed 2021 Event 3 score of 0% antibody detection, 2022 Event 2 score of 0% antibody detection 2) A review of API showed 2021 Event 3 score of 0% antibody detection, 2022 Event 2 score of 0% antibody detection</p>
D2181	<p>COMPATIBILITY TESTING CFR(s): 493.863(e)</p> <p>Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review of CMS 155D and API performance evaluation for 2021 and 2022 showed that the laboratory failed to achieve an overall score of satisfactory for 2 out of 3 testing events resulting in unsuccessful performance for compatibility testing for 2021 3rd event and 2022 2nd event. Findings: 1) A review of 155D showed 2021 Event 3 score of 0% compatibility testing, 2022 Event 2 score of 0% compatibility testing 2) A review of API showed 2021 Event 3 score of 0% compatibility testing, 2022 Event 2 score of 0% compatibility testing</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of CMS 155D and API performance evaluation for 2021 and 2022 the laboratory director failed to provide overall management and direction to the lab for successful participation in proficiency testing. (See D6016)</p>
D6016	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p>

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on record review of CMS 155D and API performance evaluation for 2021 and 2022 showed that the laboratory failed to attain satisfactory scores for 2 out of 3 testing events resulting in unsuccessful performance for the analytes of Infectious mononucleosis and Rheumatoid Factor for 2021 3rd event and 2022 2nd event. (See D2084)

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of CMS 155D and API performance evaluation for 2021 and 2022 the laboratory director failed to provide overall management and direction to the lab for successful participation in proficiency testing. (See D6089)

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:
Record review of CMS 155D and API performance evaluation for 2021 and 2022 showed that the laboratory failed to attain satisfactory scores for 2 out of 3 testing events resulting in unsuccessful performance for ABO, D, antibody detection and compatibility testing for 2021 3rd event and 2022 2nd event. (See D2162, D2163, D2172 and D2181)