

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1057922	(X3) Date Survey Completed 10/09/2019
Name of Provider or Supplier Trinity Health Medical Group, Primary Care -	Street Address, City, State 3290 N Wellness Dr Suite 220, Holland, MI	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #2 (TC2), the laboratory failed to follow established policies to assess competency for 1 (Technical Consultant #1/Clinical Consultant) of 2 laboratory personnel listed on the CMS 209 form. Findings include: 1. A record review of the laboratory's established "Personnel Competency Policy" revealed a section stating, "The Clinical Consultant and Technical Consultant are required to complete an annual competency on their federal regulatory responsibilities." 2. The surveyor requested the annual competency records on 10/9/19 at 11:22 am and the records were not made available. 3. An interview on 10/9/19 at 11:22 am with TC2 confirmed annual competencies were not available for Technical Consultant #1/Clinical Consultant.</p>
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>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 preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #2, the laboratory failed to establish a quality assessment procedure to monitor preanalytic systems in</p>

the established Individualized Quality Control Plan for 2 (October 2017 to October 2019) of 2 years. Findings include: 1. A record review of the laboratory's established "Individualized Quality Control Plan (IQCP)" policy revealed a section stating, "IQCP implementation involves completing a: Risk Assessment, QC Plan, and QA Assessment Plan." 2. A record review of the laboratory's established IQCP revealed a lack of quality assessment plan. 3. The surveyor requested the IQCP quality assessment plan on 10/9/19 at 12:22 pm and it was not made available. 4. An interview on 10/9/19 at 12:22 pm with TC2 confirmed the laboratory did not establish a quality assessment plan as part of the IQCP.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
. Based on record review and interview with Technical Consultant #2, the laboratory failed to establish a quality assessment procedure to monitor analytic systems in the established Individualized Quality Control Plan for 2 (October 2017 to October 2019) of 2 years. Findings include: 1. A record review of the laboratory's established "Individualized Quality Control Plan (IQCP)" policy revealed a section stating, "IQCP implementation involves completing a: Risk Assessment, QC Plan, and QA Assessment Plan." 2. A record review of the laboratory's established IQCP revealed a lack of quality assessment plan. 3. The surveyor requested the IQCP quality assessment plan on 10/9/19 at 12:22 pm and it was not made available. 4. An interview on 10/9/19 at 12:22 pm with TC2 confirmed the laboratory did not establish a quality assessment plan as part of the IQCP.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
. Based on record review and interview with Technical Consultant #2, the laboratory failed to establish a quality assessment procedure to monitor postanalytic systems in the established Individualized Quality Control Plan for 2 (October 2017 to October 2019) of 2 years. Findings include: 1. A record review of the laboratory's established "Individualized Quality Control Plan (IQCP)" policy revealed a section stating, "IQCP implementation involves completing a: Risk Assessment, QC Plan, and QA Assessment Plan." 2. A record review of the laboratory's established IQCP revealed a lack of quality assessment plan. 3. The surveyor requested the IQCP quality assessment plan on 10/9/19 at 12:22 pm and it was not made available. 4. An interview on 10/9/19 at 12:22 pm with TC2 confirmed the laboratory did not establish a quality assessment plan as part of the IQCP.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Technical Consultant #2 (TC2), the laboratory director failed to specify the duties of each consultant and each person performing preanalytic, analytic, and postanalytic phases of testing for 2 (October 2017 to October 2019) of 2 years. Findings include: 1. A record review of personnel files and the laboratory procedure manual revealed a lack of documentation of duties for each person performing preanalytic, analytic, and postanalytic phases of testing. 2. An interview on 10/9/19 at 11:22 am with TC2 confirmed the laboratory director did not specify the duties of each person involved in laboratory testing.