

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D0521878	<b>(X3) Date Survey Completed</b>  11/18/2020
<b>Name of Provider or Supplier</b>  Digestive Health Clinic Llc	<b>Street Address, City, State</b>  6259 W Emerald St, Boise, ID	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5291</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the laboratory director on 11/18/20, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. The findings include: 1. The laboratory has no written policies or procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements such as temperatures out of range for testing instruments. See D5781 2. An interview with the laboratory director on 11/18/2020 at 3:50 pm, confirmed that the laboratory had failed to establish and follow a quality assessment policy and procedure to monitor, assess, and, when indicated, correct problems identified in the laboratory.</p>
<b>D5781</b>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test</p>

results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of temperature logs from 8/8/2018 to 11/18/2020 and an interview with testing person on 11/18/2020, the laboratory failed to document all corrective actions taken, including actions taken when the test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications. The findings include: 1. A random review of temperature logs for the embedding center and the cold plate from 8/8/2018 to 11/18/2020 revealed that the temperatures were out of range for the right tray, left tray and the cold plate for the month of August, September and October of 2020. Right tray temperature range on the log is 58-61C, in the month of: August, 2020 twenty one (21) of twenty one (21) days were out of range. September, 2020 twenty one (21) of twenty (21) one days were out of range. October, 2020 twenty one (21) of twenty (21) one days were out of range. Left tray temperature range on the log is 68-71C, in the month of: August, 2020 twenty one (21) of twenty one (21) days were out of range. September, 2020 twenty one (21) of twenty one (21) days were out of range. October, 2020 twenty one (21) of twenty one (21) days were out of range. Cold plate temperature range on the log is -0.5-0.0C, in the month of: August, 2020 twenty (20) of twenty one (21) days were out of range. September, 2020 twenty one (21) of twenty one (21) days were out of range. October, 2020 twenty one (21) of twenty one (21) days were out of range. 2. The laboratory had no documentation of corrective actions taken for the out of range temperatures for the right tray, left tray or the cold plate. 3. The testing person confirmed by interview on 11/18/2020 at 2:35 pm that the laboratory did not take corrective actions for the out of range temperatures on the right tray, left tray and the cold plate. 4. In August, 2020 the laboratory had 782 cases and 1501 blocks, in September, 2020 the laboratory had 784 cases and 1448 blocks and in October, 2020 the laboratory had 734 cases and 1460 blocks.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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.

This STANDARD is not met as evidenced by:

Based on review of annual competency records and an interview with the laboratory director (LD)/ technical supervisor (TS), on 11/18/2020, the laboratory failed to evaluate the competency of all testing personnel listed on the the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, assuring that the staff maintain their competency to perform test procedures accurately and promptly. The findings include: 1. The laboratory's CMS-209 form identifies three (3) testing personnel performing high complexity testing procedures. The technical supervisor failed to sign

and date the competency assessment for one (1) of three testing personnel for 2019. The testing personnel also failed to sign the competency assessment for 2019. 2. The technical supervisor failed to sign and date the competency assessment for one (1) of three testing personnel from the CMS-209 form for 2020. 3. It was confirmed by interview with the LD/TS, on 11/18/2020 at 3:26 pm, that the competency assessment for one (1) of three testing personnel for 2019 and 2020 was not signed.