

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2120776	<b>(X3) Date Survey Completed</b>  01/20/2022
<b>Name of Provider or Supplier</b>  Chabado Genomics Inc	<b>Street Address, City, State</b>  3870 Del Amo Blvd Ste 502, Torrance, CA	
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>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on touring and observation of the laboratory facility, review of the refrigerator /freezer temperature records, and interview with the testing personnel (TP), it was determined that the laboratory failed to follow the manufacturer's instructions to monitor the digital thermometers, and in a manner that provides test results within the laboratory's stated performance specifications for each test system. The findings included the followings: a. The laboratory selected Fisher Scientific digital thermometers (DT) to monitor the temperature conditions for the laboratory's storage purposes. b. The DT equipped with, but not limited to, the following features: "Lo /Hi", "Min/Max", "current temperature", " Alarm On/Off", "Reset" etc. c. Observed a DT, Ref-2, a LO/Hi were set at -20 to -15 oC, while the Min/Max indicated -21.59 and 14.98. d. The alarm was OFF at the time of survey 1/20/22 @2:45 PM and when turned on, the alarm went off, indicated that in the past (?) the temperature condition was out of the acceptable temperature range the laboratory had established. e. Based on interview of the TP, it appeared that the TP did not familiarize the DT feature and failed to follow the manufacturer's instruction.</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</p>

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 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 touring and observation of the laboratory facility, review of the refrigerator/freezer temperature records, and interview with the testing personnel (TP), it was determined that the laboratory failed to perform and document all corrective actions taken, when the test system/digital thermometer failed to meet the laboratory's verified or established performance specifications, such as outside of established acceptable temperature range. The findings included the followings: a. The laboratory selected Fisher Scientific digital thermometers (DT) to monitor the temperature conditions for the laboratory's storage purposes. b. The DT equipped with, but not limited to, the following features: "Lo/Hi", "Min/Max", "current temperature", "Alarm On/Off", "Reset" etc. c. Observed a DT, Ref-2, a LO/Hi were set at -20 to -15 oC, while the Min/Max indicated -21.59 and 14.98, which were outside of the acceptable temperature range, see D-5411

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on touring and observation of the laboratory facility, review of the refrigerator/freezer temperature records, and interview with the testing personnel (TP), it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included the followings: a. The laboratory selected Fisher Scientific digital thermometers (DT) to monitor the temperature conditions for the laboratory's refrigerator/freezer storage purposes. b. The DT equipped with, but not limited to, the following features: "Lo/Hi", "Min/Max", "current temperature", "Alarm On/Off", "Reset" etc. c. Observed a DT for Ref-2, a LO/Hi were set at -20 to -15 oC, while the Min/Max indicated -21.59 and 14.98, which were outside of the acceptable temperature range, See D-5411 d. The laboratory failed to perform and document all corrective actions taken, when the test system/digital thermometer failed to meet the laboratory's verified or established performance specifications, such as outside of established acceptable temperature range, see D-5781