

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D0410131	<b>(X3) Date Survey Completed</b>  07/26/2021
<b>Name of Provider or Supplier</b>  Logan Health Conrad	<b>Street Address, City, State</b>  805 Sunset Blvd, Conrad, MT	
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>D2016</b>	<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 record review of American Proficiency Institute (API) proficiency testing scores and interview with the Technical Supervisor (TS) #1, the laboratory failed to achieve satisfactory performance for specialties mycology and immunohematology for 2 out of 3 events in 2019 and 2020 and failed to undertake appropriate training and employ the technical assistance necessary to correct problems associated with immunohematology proficiency testing failures. (See D2028, D2188 and D2190)</p>
<b>D2046</b>	<p>MYCOLOGY CFR(s): 493.827(e)</p>

Failure to achieve an overall testing event score of satisfactory performance 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 American Proficiency Institute (API) proficiency testing scores and interview with the Technical Supervisor (TS) #1, the laboratory failed to achieve a satisfactory performance score of 80% or better for KOH preparation (glass slide) for two of three events (2019 Event 3 and 2020 Event 2), resulting in unsuccessful proficiency testing performance. Findings: 1. Review of American Proficiency Institute (API) proficiency testing scores revealed the laboratory scored 50% for 2019 Event 3 and 2020 Event 2. 2. Interview with the TS #1 on July 26, 2021 at 3:06 PM confirmed the laboratory failed to achieve a satisfactory performance for two of three events for KOH preparation (glass slide) for 2019 and 2020.

**D2188**

ANTIBODY IDENTIFICATION

CFR(s): 493.865(d)

(1) For any unsatisfactory 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 unsatisfactory 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.

This STANDARD is not met as evidenced by:

. Based on record review of American Proficiency Institute (API) proficiency testing scores for Immunohematology and interview with the Technical Supervisor (TS) #1, the laboratory failed to undertake appropriate training and employ the technical assistance necessary to correct problems associated with the unsuccessful proficiency testing for 2020. Findings: 1. Review of American Proficiency Institute (API) proficiency testing scores for 2020 Immunology/Immunohematology revealed unsuccessful proficiency testing for Compatibility Testing; Event 3, DAT-Anti-IgG; Event 2 and Event 3. 2. The laboratory failed to perform and document remedial training of personnel and to employ the technical assistance necessary to correct problems associated with repeat proficiency testing failure. 3. Interview with the TS #1 on July 26, 2021 at 3:30 PM confirmed the laboratory failed to perform and document remedial training and employ the technical assistance necessary to correct problems associated with the unsuccessful proficiency testing.

**D2190**

ANTIBODY IDENTIFICATION

CFR(s): 493.865(e)

Failure to identify the same antibody in two consecutive or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on record review of American Proficiency Institute (API) proficiency testing scores and interview with the Technical Supervisor (TS) #1, the laboratory failed to

achieve a satisfactory performance score of 80% or better for DAT-Anti-IgG for two of three events (2020 Event 2 and 2020 Event 3), resulting in unsuccessful proficiency testing performance. Findings: 1. Review of American Proficiency Institute (API) proficiency testing scores for DAT-Anti-IgG revealed the laboratory scored a 50% for 2020 Event 2 and Event 3. 2. Interview with the TS #1 on July 26, 2021 at 3:10 PM confirmed the laboratory failed to achieve a satisfactory performance for two of three events for DAT-Anti-IgG for 2020.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:  
. Based on review of the calibration records for the Siemens Dimension EXL 200 chemistry analyzer for the analytes of sodium, potassium, and chloride, and interview with the Technical Supervisor (TS) #1, the laboratory failed to perform at least a three point (a minimal, mid-point, and maximum) calibration verification every six months. Findings: 1. Review of 2019 and 2020 calibration records for the Siemens Dimension EXL 200 chemistry analyzer for the analytes: sodium, potassium, and chloride, revealed the laboratory failed to perform a calibration including, at least, a minimal, midpoint, and maximum value for each analyte, every six months. 2. Interview with the TS #1 on July 26, 2021 at 11:52 AM confirmed the laboratory failed to perform at least a three-point calibration for sodium, potassium, and chloride on the Siemens Dimension EXL 200 chemistry analyzer every six months.

**D5471**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and

negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Technical Supervisor (TS) #1, the laboratory failed to document the quality check of each new lot number, and shipment for positive and negative reactivity for bacitracin, catalase, Cefinase, oxidase, PYR disks, staphylococcal latex for year 2020. Findings: 1. Review of Bacteriology QC Log sheet lacked documentation for quality check for positive and negative reactivity for new lot number and shipment of bacitracin, catalase, Cefinase, oxidase, PYR disks, staphylococcal latex for year 2020. 2. Pondera Medical Center Laboratory procedure states " The following tests are used in this laboratory and QC are performed as noted: gram stain-weekly, bacitracin-each new lot# and shipment, catalase-each new lot# and shipment, Cefinase- each new lot# and shipment, staph latex- each new lot# and shipment, oxidase- each new lot# and shipment, PYR- each new lot# and shipment" 3. Interview on July 26, 2021 at 11:15 AM with TS #1 confirmed the laboratory failed to document the quality check for positive and negative reactivity for new lot number and shipment of bacitracin, catalase, Cefinase, oxidase, PYR disks, staphylococcal latex for year 2020.