

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0646339	(X3) Date Survey Completed 11/15/2023
Name of Provider or Supplier Idaho Bureau Of Laboratories	Street Address, City, State 2220 Old Penitentiary Road, Boise, ID	
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
D5305	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.</p> <p>This STANDARD is not met as evidenced by: Based on a review of patient records, the laboratory's Standard Operating Procedures (SOP), and interviews by the Laboratory Director (LD) and Technical Supervisors (TS), the laboratory failed to document (ND) the temperatures and media when SARS-CoV2 patient specimens are received. Findings include: 1. A review of six (6) of Six (6) SARS CoV2 patient specimens in 2022 and 2023, revealed the laboratory failed to document the temperature and media type upon receipt of SARS CoV2. Spec ID Collected Received Temp/Media C220301725 03/07/2022 03/08/2022 ND C220702307 07/13/2023 07/14/2022 ND C221001205 10/14/2022 10/17/2022 ND C230100764 01/10/2023 01/12/2023 ND C230400005 03/31/2023 04/03/202 ND C230800582 08/13/2023 08/14/2023 ND 2. The laboratory's Virology department SOP requires specimens not received within 72 hours of collection to be frozen at negative 70 degrees if submitted on VTM media or at room temperature if submitted</p>

on ITM media. 3. One (1) of six (6) SARS-CoV2 patient specimens received were outside of the 72-hour receipt for the testing time frame. The laboratory did not have documentation of the temperature or the type of media at the time the specimen was received. C230400005-001 Collected 03/31/2023@00:00 received 04/03/2023@10:32, test performed 04/05/2023@15:34. 4. The Virology TS confirmed during an interview on 11/14/2023 at 142:30 PM, the lack of documentation of temperatures and media type of the SARS-CoV2 patient specimens received. 5. The laboratory reports performing approximately 8113 SARS CoV2 SARS CoV2 patient specimens annually.

D5309

TEST REQUEST
CFR(s): 493.1241(e)

If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.

This STANDARD is not met as evidenced by:
Based on the review of the laboratory's test requisitions, patient test reports, and interview with the laboratory Virology Technical Supervisor (VTS) the laboratory failed to ensure the accuracy of patient information manually entered in the laboratory's information system (LIMS). Findings include: 1. A review of 17 patient records revealed that one (1) of 17 patient records had the date of birth (DOB) from the requisition submitted and the DOB entered in the laboratory LIMS, as different dates. Accession ID DOB Requisition DOB Patent Report C230800567-001 06/17/2008 06/18/2008 2. The laboratory VTS confirmed by an interview on 11/15/2023 at 10:20 AM the inaccurate entry of the patient's DOB into the LIMS system. 3. The laboratory reports performing 9,194 patient tests annually.

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 a review of patient records, a lack of a laboratory's Quality Assessment (QA) policies or procedures, and an interview with the Laboratory Director (LD) and Technical Supervisors (TS), the LD failed to establish a QA plan to monitor, assess, and correct problems for all facets of the laboratory processes to ensure quality laboratory patient testing. Findings include: 1. A review of the laboratory's patient records revealed a lack of documentation on patient requisitions and a discrepancy of a patient testing report for seven (7) of 17 patient records from March 08, 2022, through August 14, 2023. See D5305, D5304 Specimen ID C220301725-001- Lack of documentation C220702307-001- Lack of documentation C230800567-001- Lack of documentation C221001205-001- Lack of documentation C230100764-001- Lack of documentation C230400005-001- Lack of documentation C230800582-001- Data entry error 2. A request for the laboratory's QA policies and procedures revealed the lack of QA policies or procedures having been established by the LD for an ongoing review process to monitor pre-analytic, analytic, and post-analytic patient testing. 3.

The LD and TS confirmed during the interview on 11/13/2023 at 12:30 PM, the lack of QA policies or procedures being established. 4. The laboratory reports performing 9,194 patient tests annually.