

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2117825	(X3) Date Survey Completed 09/04/2020
Name of Provider or Supplier Interlab Corp	Street Address, City, State 9000 Nw 15th St Unit 1a, Doral, FL	
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
D0000	A recertification survey conducted on 09/02/2020 to 09/04/2020 found that Interlab Corp clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2089	<p>ROUTINE CHEMISTRY CFR(s): 493.841(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to participate in American Association of Bioanalysts (AAB) proficiency testing (PT) for Routine Chemistry that resulted in a score of 0% for the third PT event in 2019 . Findings Included: A review of 2019 AAB proficiency testing revealed a score of 0% for Routine Chemistry along with the following analytes: Alanine Aminotransferase, albumin, amylase, Aspartate Aminotransferase, bilirubin total, Calcium total, cholesterol total, high-density lipoprotein. Creatine kinase total, creatinine total , glucose total , low-density lipoprotein, Magnesium, Potassium , sodium , total protein, Triglyceride, blood urea nitrogen and uric acid. During an interview on 09/04/20 at 12:30 PM, technologist A confirmed Routine Chemistry PT was not performed during the third event in 2019.</p>
D2100	ENDOCRINOLOGY

CFR(s): 493.843(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to participate in American Association of Bioanalysts (AAB) proficiency testing (PT) for Endocrinology that resulted in a score of 0% for the third PT event in 2019. Findings Included: A review of 2019 AAB proficiency testing revealed a score of 0% for Endocrinology with the following analytes: cortisol, Free Tyrosine, Human chorionic gonadotropin, thyroid function (T3 uptake), Thyroid-Stimulating Hormone, Tyrosine and triiodothyronine. During an interview on 09/04/20 at 12:30 PM, technologist A confirmed Endocrinology PT was not performed during the third event in 2019.

D3037

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to keep documentation for the third proficiency testing (PT) event in 2018 from American Association of Bioanalysts (AAB). Findings Include: A review of AAB proficiency testing record revealed no documentation of PT records for the third testing event in 2018. During an interview on 09/04/20 at 12:30 PM, the technologist B confirmed that there was no documentation of PT records for the third testing event in 2018.

D5609

HISTOPATHOLOGY

CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to document and maintain a record of the open date, lot number and expiration date for Quik- Dip (QD) Stain for 2 years reviewed (from 8/2018 to 8/2020). Findings Include: Record review of reagent log documentation for Histology section, revealed that there was no record of open date, lot number and expiration date for QD Stain reagents used from 8/2019

to 9/2020. During an interview on 09/02/20 at 1:30 PM with the Cytology Supervisor, she confirmed that there was no documentation of the QD stain reagent lot and expiration dates.

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 observation, record review and staff interview, the laboratory failed to follow their Quality assessment (QA) checklist and document when their AU680 Beckman Coulter instrument for chemistry was no longer in use due to flooding damage. Findings Included: A review of proficiency testing records revealed that AU680 Beckman Coulter instrument was performing chemistry testing from 2018 to June 22, 2020. A review of 2020 QA checklist displayed no documentation of the AU680 Beckman Coulter not in use during June 2020. An observation of the chemistry testing room revealed that there was no AU680 Beckman Coulter present or being used. During an interview on 09/04/20 at 12:30 PM, technologist B stated the AU680 Beckman Coulter was damaged and removed due to a flooding on June 25, 2020 and confirmed the instrument's removal was not documented in their QA checklist.