

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2020658	(X3) Date Survey Completed 03/10/2023
Name of Provider or Supplier Corinthian Reference Lab	Street Address, City, State 6201 Southwest Blvd, Benbrook, TX	
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	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedures, accuracy assessments, grossing logs, pre-survey paperwork, and interview, the laboratory failed to verify the accuracy of its grossing of skin punch biopsies used in the interpretation of neuropathies in dermatopathology specimens at least twice annually for 2 of 2 years reviewed in 2021 and 2022. Findings follow. A. Review of the laboratory's policy and procedure titled Grossing, OPS. 020 effective 09/28/2022, under Policy stated, "All specimens received will be visually examined, measured, and described by qualified personnel. Pictures will be taken and sent with grossing report to the pathologist within 24 hours of receiving specimens. The grossing report will have all documentation including irregularities of tissue. B. Accuracy assessments for grossing skin punch biopsies were requested on March 2, 2023, at 1035 hours but not provided. C. Random review of the grossing log for 08/16/2022 showed case #s 2686 - 2704, 18 cases, were grossed. D. Review of the pre-survey paperwork CMS form 116 showed an annual test volume of approximately 11,700 specimens for grossing. E. Interview with the Laboratory Manager/Testing Personnel #3 as listed on the CMS form 209, on March 2, 2023, at 1035 hours confirmed accuracy assessments for grossing were not performed.</p>
D5601	HISTOPATHOLOGY

CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

I. Based on review of the laboratory's policies and procedures, quality control (QC) records, and interview, the laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the CD3 Immunohistochemical (IHC) stain used for the visual detection of autoimmune inflammatory detection in skin biopsies used in the interpretation of neuropathies in dermatopathology specimens for at least 2 of 59 days of testing reviewed. Finding follow. A. Review of the laboratory's policy and procedure titled CD3 Staining Protocol, OPS. 016.R06 effective 09/28/2022, under Quality Control stated, "Stain characteristics for positive and negative reactivity to ensure stain quality: Stain adequacy has been attained when T-cells are stained brown, but the collagen is not (positive result). A negative test will exhibit no brown stained T-cells." B. Review of the CD3 IHC Stain Assessment QA Log from 09/28/22 - 12/30/22 showed the following gaps in QC: 1. Gap in QC from 12/16/22 - 12/22/22 for case numbers 4142 - 4188 and 2. Gap in QC from 10/01/22 - 10/05/22 for case numbers 3209 - 3225. C. Interview with the Laboratory Manager/ Testing personnel #3 as listed on the CMS form 209, on March 2, 2023, at 1325 hours confirmed they should be putting the [QC] sheets in order and making sure they all come back. II. Based on review of the laboratory's policies and procedures, QC records, and interview, the laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the PGP 9.5 IHC stain used for the diagnosis of small fiber neuropathy used in the interpretation of neuropathies in dermatopathology specimens for at least 2 of 62 days of testing reviewed. Finding follow. A. Review of the laboratory's policy and procedure titled PGP 9.5 Immunohistochemistry, OPS.009-R07 effective 09/28/2022, under Quality Control stated, "Stain characteristics for positive and negative reactivity to ensure stain quality: Stain adequacy has been attained when long continuous segments of nerve tissue are visible in the dermis and epidermis in the color corresponding to the Chromogen in use (Generally blue). Determination of positive results are made by quantification of the nerve fibers in the epidermis and comparison with reference normative data." B. Review of the PGP 9.5 Stain QA Log from 09/30/22 - 12/15/22 showed the following gaps in QC: 1. Gap in QC from 11/23/22 - 11/28/22 for case numbers 3828 - 3834 and 2. Gap in QC from 11/17/22 - 11/23/22 for case numbers 3760 - 3792. C. Interview with the Laboratory Manager/ Testing personnel #3 as listed on the CMS form 209, on March 2, 2023, at 1325 hours confirmed they should be putting the [QC] sheets in order and making sure they all come back.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5)

Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of patient test reports and interview, the laboratory failed to include the name of the reference laboratory for the interpretation of neuropathies in dermatopathology specimens for ten of twelve reports reviewed. Findings follow. A. Random review of twelve test reports showed ten were missing the name of the reference laboratory: Report date Specimen # 1. 02/28/23 S23.0498 2. 11/17/22 S22.3658 3. 09/02/22 S22.2764 4. 07/22/22 S22.2298 5. 04/21/22 S22.1122 6. 04/21/22 G22.0334 7. 12/22/21 S21.4028 8. 10/14/21 S21.3114 9. 09/03/21 S21.2592 10. 04/15/21 S21.0864 B. Interview with the General Manager/Testing personnel #2 as listed on the CMS Form 209, on March 10, 2023, at 1345 hours via phone call confirmed the findings.