

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2294566	(X3) Date Survey Completed 03/14/2024
Name of Provider or Supplier Southern Crescent Neurological Clinic Pc	Street Address, City, State 16922 Telge Rd, Suite 2b, Cypress, 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	An announced survey of the laboratory was conducted on 03/14/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). STANDARD LEVEL DEFICIENCIES were cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, personnel records and staff interview, the laboratory failed to follow its own policy for documentation of personnel competency assessment for 4 of 4 personnel employed by the facility in 2023 and 2024. Findings included: 1. Review of laboratory's policy "Training and Competency Program" (approved by laboratory director 11/14/2023) revealed: "At the end of the competency period, the director or supervisor is responsible for determining if the employee has successfully completed the competency assessment process using the defined verification tools and methods." 2. Review of laboratory's policy "Delegation of Duties by the Laboratory Director: Technical/General Supervisor" (approved by laboratory director 11/14/2023) revealed: "Competencies - Completes competency assessment for each employee initially, 6 month and annually (sic)" 3. Review of laboratory's personnel records revealed the initial Testing Personnel competency assessments were signed off by the laboratory's Executive (as indicated on the submitted Survey Entrance/Exit Conference document), not by the Technical Supervisor. 4. Review of laboratory's personnel records revealed the initial Technical Supervisor and General Supervisor competency assessments were signed off by the laboratory's Executive (as indicated on the submitted Survey Entrance/Exit Conference document), not by the Laboratory Director. 5. In an interview on 03/14</p>

/2024 at 1130 hours in the laboratory, the Technical Supervisor (as indicated on submitted Form CMS 209) confirmed the findings.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

A. Based on review of laboratory's policies/procedures, instructions to providers, specimen receipt logs and staff interview, the laboratory failed to ensure providers follow laboratory's policy for sample acceptance criteria and use Sample Shipment Documentation Form for 4 of 4 shipment documents reviewed for February 2024. Findings included: 1. Review of laboratory's policy "Urine Collection, Storage and Transport for Toxicology Testing v2" (approved by laboratory director 12/16/2023) revealed: "Acceptance Criteria ... Use of a Sample Shipment Documentation Form" 2. Review of laboratory's instructions to providers on the "Sample Shipment Documentation" form revealed: "Please fill out this sheet out and its entirety (sic). Please include one sheet in each shipment." 3. Review of laboratory's scanned specimen receipt logs revealed there were no Sample Shipment Documentation forms with each shipment. 4. In an interview on 03/14/2024 at 1010 hours in the laboratory, the General Supervisor (as indicated on submitted Form CMS 209) confirmed that providers did not submit the Sample Shipment Documentation forms with each shipment. B. Based on review of laboratory's policies/procedures, personnel records and staff interview, the laboratory failed to follow its own policy for documentation of training for 4 of 4 testing personnel employed by the facility in 2023 and 2024. Findings included: 1. Review of laboratory policy "Training and Competency Program" (approved by laboratory director 11/14/2023) revealed: "New employees are oriented and their full competency is validated during the training period." And, "Checklists are used as a training tool to ensure all steps within the process are addressed and reviewed. They are not designed to serve as final competency review /sign off." 2. Review of laboratory's personnel records revealed there were no checklists documented as part of the training of testing personnel. No other documentation designated as "training" was available for review. 3. In an interview on 03/14/2024 at 1150 hours in the laboratory, the Technical Supervisor (as indicated on submitted Form CMS 209) confirmed that the training checklists were not documented.

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 laboratory's random patient test reports and staff interview, the laboratory failed to include specimen source on the final report for 10 of 10 final reports reviewed from March 2024. Findings included: 1. Review of laboratory's random patient test reports from March 2024 revealed the final reports for the following accession numbers did not have specimen source specified on the report: Accession: 23992 23996 23997 23998 23999 24007 24011 24022 24035 24036 3. In an interview on 03/14/2024 at 1010 hours in the laboratory, the Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid