Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0930963	11/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Special Tree Neuro Care Center	10909 Hannan Rd, Romulus, MI	

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
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #2 (TC2), the laboratory failed to retain risk assessment documentation used in the laboratory's quality control plan for the Abaxis Piccolo Xpress chemistry system for the quality control plan in use for 2 (November 2019 to November 2021) of 2 years reviewed. Findings include: 1. The surveyor requested the Abaxis Piccolo Xpress chemistry system's Individualized Quality Control Plan (IQCP) on 11/22/21 at 1:12 pm. 2. A review of the Abaxis Piccolo IQCP revealed a lack of supporting documentation of the risk assessment performed for the quality control plan. 3. An interview on 11/22 /21 at 1:12 pm with TC2 confirmed the laboratory did not retain the risk assessment documentation used in the laboratory's quality control plan.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to follow the manufacturer's calibration verification instructions for the Abaxis Piccolo Xpress chemistry system. Refer to D5439.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on record review, observation, and interview with Technical Consultant #2 (TC2), the laboratory failed to update the expiration date on hematology quality control materials reflecting the stability of opened vials for 3 (low, normal, high) of 3 quality control vials observed. Findings include: 1. A review of the laboratory's hematology quality control package insert revealed the expiration date of open vials is 35 days. 2. The surveyor observed the laboratory's hematology quality control materials on 11/22/21 at 10:16 am and noted the 11/11/21 open date of the controls on a urine cup used to house the controls and an expiration date of 2/14/22 on each of the quality control vials. 3. An interview on 11/22/21 at 1:42 pm with TC2 confirmed the laboratory did not update the hematology quality control expiration dates to reflect the 35-day open vial stability.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation and interview with Technical Consultant #2 (TC2), the laboratory failed to ensure the reagents for the Beckman Coulter AcT Diff hematology analyzer did not exceed their expiration date for 35 (10/18/21 to 11/22/21) days since the reagent was in use. Findings include: 1. The surveyor observed the laboratory's Beckman Coulter AcT Diff hematology analyzer during a tour of the laboratory on 11 /22/21 at 9:10 am. The "COULTER diff AcT PAK" reagent kit connected to the analyzer had an expiration date of 3/16/21. The date 10/18/21 was written on the box as the date the reagent was loaded on the analyzer for use. 2. An interview on 11/22 /21 at 9:10 am with TC2 confirmed the laboratory had been using an expired reagent for its hematology testing since 10/18/21 when it was loaded on the analyzer.
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 a lack of documentation and interview with Technical Consultant #2 (TC2), the laboratory failed to follow the manufacturer's calibration verification instructions for the Abaxis Piccolo Xpress chemistry system for 2 (November 2019 to November 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Abaxis Introduction" document revealed a section titled "6 Month Verification" stating, "Linearity verification can be performed every 6 months, however due to recent CMS/CLIA changes this may be optional. The lab director should check with the state CLIA office or accrediting agency for requirements." 2. The surveyor requested additional documentation that may show the test system did not require calibration verification on 11/22/21 at 11:42 am and it was not made available. 3. An interview on 11/22/21 at 2:43 pm with TC2 confirmed the Abaxis Piccolo Xpress chemistry system did require calibration verification to be performed every 6 months and had not previously been performed.
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 record review and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure positive patient identification on test reports for 9 (Patients 1, 2, 3, 4, 6, 7, 8, 9, and 10) of 10 patient test reports reviewed. Findings include: 1. A review of patient test reports revealed reports from the Abaxis Piccolo Xpress

	chemistry system did not include a full patient name to be used in conjunction with an identification number for Patients 1, 2, 3, 4, 6, 7, 8, 9, and 10. 2. An interview on 11 /22/21 at 12:05 pm with TP1 confirmed patients receiving testing on the Abaxis Piccolo Xpress chemistry system did not include a full patient name to be used in conjunction with an identification number to ensure positive patient identification.