Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1092331	04/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Transcend Medical Group	1119 W Randol Mill Road , Suite 103, Arlington, 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 unannounced onsite complaint survey was completed on 04/16/2025 for intake # TX00537504. The laboratory was found to be in compliance with the CLIA regulations for specialties/subspecialties surveyed for 42 CFR. The complaint was substantiated.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) evaluation form, review of the laboratory's instrument data, review of the laboratory's policy, and confirmed in interview, the laboratory failed to ensure PT results documented by the laboratory correlated with results submitted to the PT agency for one of one PT events in 2025 (2025 Event 1). Findings include: 1. Review of the API PT evaluation form determined the following results submitted by the laboratory were graded by the PT provider: 2025 Hematology / Coagulation - 1st Event: a. Sample ID: DXH-01 WBC: 7.3 x10^3/L RBC: 4.70 x10^6/L Hemoglobin: 14.3 g/dL Hematocrit: 41.1 % MCV: 87.5 fL MCH: 30.5 pg MCHC: 34.9 g/dL RDW-CV: 13.3 % RDW-SD: 48.3 % Platelet: 244 x10^3/L MPV: 8.4 fL Lymphocytes, %: 27.0 Monocytes, %: 0.0 Neutrophils, %: 69.4 Eosinophils, %: 3.6 Basophils, %: 0.0 b.

Sample ID: DXH-02 WBC: 2.3 x10^3/L RBC: 2.30 x10^6/L Hemoglobin: 6.5 g/dL Hematocrit: 19.1 % MCV: 83.9 fL MCH: 28.6 pg MCHC: 34.2 g/dL RDW-CV: 13.9 % RDW-SD: 48.1 % Platelet: 71 x10^3/L MPV: 9.6 fL Lymphocytes, %: 43.7 Monocytes, %: 0.2 Neutrophils, %: 44.7 Eosinophils, %: 11.4 Basophils, %: 0.00 c. Sample ID: DXH-03 WBC: 7.4 x10^3/L RBC: 4.70 x10^6/L Hemoglobin: 14.5 g/dL Hematocrit: 41.1 % MCV: 88.1 fL MCH: 31.0 pg MCHC: 35.3 g/dL RDW-CV: 13.5 % RDW-SD: 48.5 % Platelet: 240 x10^3/L MPV: 8.4 fL Lymphocytes, %: 27.1 Monocytes, %: 1.2 (Unacceptable) Neutrophils, %: 67.1 Eosinophils, %: 3.5 Basophils, %: 1.1 (Unacceptable) d. Sample ID: DXH-04 WBC: 18.0 x10^3/L RBC: 5.00 x10^6/L Hemoglobin: 17.4 g/dL Hematocrit: 48.7 % MCV: 97.5 fL MCH: 34.9 pg MCHC: 35.7 g/dL RDW-CV: 12.4 % RDW-SD: 49.9 % Platelet: 476 x10^3/L MPV: 8.1 fL Lymphocytes, %: 13.3 Monocytes, %: 0.4 Neutrophils, %: 78.4 Eosinophils, %: 7.8 Basophils, %: 0.1 e. Sample ID: DXH-05 WBC: 2.45 x10^3/L RBC: 2.30 x10^6/L Hemoglobin: 6.6 g/dL Hematocrit: 19.5 % MCV: 84.2 fL MCH: 28.5 pg MCHC: 33.7 g/dL RDW-CV: 13.9 % RDW-SD: 48.5 % Platelet: 79 x10^3/L MPV: 9.3 fL Lymphocytes, %: 45.4 Monocytes, %: 0.1 Neutrophils, %: 43.8 Eosinophils, %: 10.7 Basophils, %: 0.1 2. Review of the laboratory's instrument raw data in the PT records determined the laboratory failed to ensure PT results documented by the laboratory correlated with results submitted to the PT agency for one of one PT events in 2025 (2025 Event 1): a. Specimen ID: 031 Date/Time: 03/06/2025 1503 hours Analyzer WBC: 7.41 x10^3/L Submitted result: 7.3 x10^3/L Analyzer RBC: 4.77 x10^6/L Submitted result: 4.70 x10^6/L Analyzer Hemoglobin: 14.76 g/dL Submitted result: 14.3 g/dL Analyzer Hematocrit: 41.8 % Submitted result: 41.1 % Analyzer MCV: 87.7 fL Submitted result: 87.5 fL Analyzer MCH: 30.9 pg Submitted result: 30.5 pg Analyzer MCHC: 35.3 g/dL Submitted result: 34.9 g/dL Analyzer RDW: 13.2 % Submitted result: 13.3 % Analyzer RDW-SD: 48.2 % Submitted result: 48.3 % Analyzer Platelet: 255.2 x10^3/L Submitted result: 244 x10^3/L Analyzer Lymphocytes: 28.09 % Submitted result: 27.0 % Analyzer Monocytes: 0.40 % Submitted result: 0.0 % Analyzer Neutrophils: 68.19 % Submitted result: 69.4 % Analyzer Eosinophils: 3.19 % Submitted result: 3.6 % Analyzer Basophils: 0.13 % Submitted result: 0.0 % b. Specimen ID: 032 Date/Time: 03/06/2025 1504 hours Analyzer WBC: 2.47 x10^3/L Submitted result: 2.3 x10^3/L Analyzer RBC: 2.34 x10^6/L Submitted result: 2.30 x10^6/L Analyzer Hemoglobin: 6.63 g/dL Submitted result: 6.5 g/dL Analyzer Hematocrit: 19.7 % Submitted result: 19.1 % Analyzer MCV: 84.0 fL Submitted result: 83.9 fL Analyzer MCH: 28.3 pg Submitted result: 28.6 pg Analyzer MCHC: 33.7 g/dL Submitted result: 34.2 g/dL Analyzer RDW: 13.8 % Submitted result: 13.9 % Analyzer RDW-SD: 46.6 % Submitted result: 48.1 % Analyzer Platelet: 80.7 x10^3/L Submitted result: 71 x10^3/L Analyzer MPV: 9.86 fL Submitted result: 9.6 fL Analyzer Lymphocytes: 42.58 % Submitted result: 43.7 % Analyzer Monocytes: 0.12 % Submitted result: 0.2 % Analyzer Neutrophils: 46.40 % Submitted result: 44.7 % Analyzer Eosinophils: 10.90 % Submitted result: 0.0 % c. Specimen ID: 033 Date/Time: 03/06/2025 1505 hours Analyzer WBC: 7.26 x10^3/L Submitted result: 7.4 x10^3/L Analyzer RBC: 4.71 x10^6/L Submitted result: 4.70 x10^6/L Analyzer Hematocrit: 41.5 % Submitted result: 41.1 % Analyzer MCH: 30.7 pg Submitted result: 31.0 pg Analyzer MCHC: 34.9 g/dL Submitted result: 35.3 g/dL Analyzer Platelet: 246.9 x10^3/L Submitted result: 240 x10^3/L Analyzer MPV: 8.32 fL Submitted result: 8.4 fL Analyzer Lymphocytes: 26.57 % Submitted result: 27.1 % Analyzer Monocytes: 0.04 % Submitted result: 1.2 % Analyzer Neutrophils: 70.08 % Submitted result: 67.1 % Analyzer Eosinophils: 3.31 % Submitted result: 3.5 % Analyzer Basophils: 0.00 % Submitted result: 1.1 % d. Specimen ID: 034 Date/Time: 03/06/2025 1507 hours Analyzer WBC: 18.05 x10^3/L Submitted result: 18.0 x10^3/L Analyzer RBC: 5.07 x10^6/L Submitted result: 5.00 x10^6/L Analyzer Hemoglobin: 17.63 g/dL Submitted

	result: 17.4 g/dL Analyzer Hematocrit: 49.6 % Submitted result: 48.7 % Analyzer MCV: 97.9 fL Submitted result: 97.5 fL Analyzer MCH: 34.8 pg Submitted result: 34.9 pg Analyzer MCHC: 35.5 g/dL Submitted result: 35.7 g/dL Analyzer RDW: 12.0 % Submitted result: 12.4 % Analyzer RDW-SD: 50.1 % Submitted result: 49.9 % Analyzer Platelet: 494.6 x10^3/L Submitted result: 476 x10^3/L Analyzer MPV: 7.96 fL Submitted result: 8.1 fL Analyzer Lymphocytes: 13.68 % Submitted result: 13.3 % Analyzer Monocytes: 0.52 % Submitted result: 0.4 % Analyzer Neutrophils: 77.09 % Submitted result: 78.4 % Analyzer Eosinophils: 8.64 % Submitted result: 7.8 % e. Specimen ID: 035 Date/Time: 03/06/2025 1508 hours Analyzer RBC: 2.27 x10^6/L Submitted result: 2.30 x10^6/L Analyzer Hemoglobin: 6.41 g/dL Submitted result: 6.6 g/dL Analyzer Hematocrit: 19.2 % Submitted result: 19.5 % Analyzer MCV: 84.7 fL Submitted result: 84.2 fL Analyzer MCH: 28.2 pg Submitted result: 28.5 pg Analyzer MCHC: 33.4 g/dL Submitted result: 33.7 g/dL Analyzer RDW: 13.7 % Submitted result: 13.9 % Analyzer RDW-SD: 47.9 % Submitted result: 48.5 % Analyzer Platelet: 70.1 x10^3/L Submitted result: 79 x10^3/L Analyzer MPV: 8.78 fL Submitted result: 9.3 fL Analyzer Lymphocytes: 43.74 % Submitted result: 45.4 % Analyzer Monocytes: 0.24 % Submitted result: 0.1 % Analyzer Neutrophils: 44.24 % Submitted result: 43.8 % Analyzer Eosinophils: 11.58 % Submitted result: 10.7 % Analyzer Basophils: 0.20 % Submitted result: 0.1 % 3. Testing person-1 (as listed on the CMS-209 form) confirmed the findings in an interview on 04/16/2025 at 1310 hours in the office. Key: WBC - white blood cell RBC - red blood cell MCV - mean corpuscular volume MCH - mean corpuscular hemoglobin MCHC - mean corpuscular hemoglobin concentration RDW-CV - red cell distribution width, coefficient of variation RDW-SD - red cell distribution width, standard deviation MPV - mean platelet volume x10^3/L - thousand per microliter x10^6/L - million per microliter g /dL - grams per deciliter % - percent fL - femtoliter pg - picogram CMS - Centers for Medicare and Medicaid Services
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, laboratory policy, temperature logs, patient final reports, and confirmed in interview, the laboratory failed to document room temperature readings for 2 of 18 patient testing days in March 2025. Findings Included: 1. During a tour of the facility on 04/16/2025 at 10:18 AM, the surveyor observed one DXH520 (Serial Number: 210613) Hematology analyzer processing patient specimens. 2. Review of Beckman Coulter DXH520 hematology analyzer manufacturer's instructions, "Instructions for Use" (Version: PN C41838AA), revealed the following acceptable operating temperature range: 18-32 Celsius 3. Review of laboratory policy, "Temperature Policy" (Approved by the Laboratory Director on 01/04/2025) revealed the following: "It is the policy of this laboratory to properly monitor temperature dependent equipment. ...The testing personnel ...attest that she has read this policy and is trained on this policy and understands that she must monitor and record the laboratory room temperature ... accordingly on the following logs. Testing personnel also understands what she must do if the temperature ever falls out of range via, the corrective action taken and that she must document the corrective action on this temperature log attached." Further review of the policy revealed the "Temp & Humidity Logs" referenced above. 4.

	Review of laboratory temperature logs, "Temp & Humidity Logs" in 2025, revealed the laboratory failed to document room temperature for two testing days in March 2025. March 2025; No documentation of room temperature readings a. 03/06/2025 b. 03/07/2025 The laboratory was asked to provide documentation of corrective actions for no room temperature documentation, for the above patient testing days in March 2025, and none was provided. 5. Random review of patient final reports in March 2025, revealed the following 17 patients tested when room temperature was not documented prior to patient testing: Patients tested on 03/06/2025 (See attached Patient Alias List) a. Patient 1 b. Patient 2 c. Patient 3 d. Patient 4 e. Patient 5 f. Patient 6 g. Patient 7 h. Patient 8 i. Patient 9 j. Patient 10 Patients tested on 03/07 /2025 k. Patient 11 l. Patient 12 m. Patient 13 n. Patient 14 o. Patient 15 p. Patient 16 q. Patient 17 6. In an interview on 04/16/2025 at 12:28 PM in the facility storage area, Testing Person 1 (TP-1), confirmed the above findings.
D5805	TEST REPORT CFR(s): 493.1291(c) (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 surveyor observation, review of patient final reports in March 2025, and confirmed in interview, the laboratory failed to document patient identification numbers on 17 of 17 patient final reports randomly reviewed in March 2025. Findings Included: 1. During a tour of the facility on 04/16/2025 at 10:18 AM, the surveyor observed one DXH520 (Serial Number: 210613) hematology analyzer processing patient specimens. 2. Random review of patient final reports in March 2025, revealed no patient identification numbers documented for the following 17 patients reviewed: Patients tested on 03/06/2025 (See attached Patient Alias List) a. Patient 1 b. Patient 2 c. Patient 3 d. Patient 4 e. Patient 5 f. Patient 6 g. Patient 7 h. Patient 8 i. Patient 9 j. Patient 10 Patients tested on 03/07/2025 k. Patient 11 l. Patient 12 m. Patient 13 n. Patient 14 o. Patient 15 p. Patient 16 q. Patient 17 The laboratory was asked to provide documentation of patient identification numbers on the above patient final reports for positive patient identification, and no documentation was provided. 3. In an interview on 04/16/2025 at 01:28 PM in the laboratory, TP-1 confirmed the above findings.