

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2030207	<b>(X3) Date Survey Completed</b>  07/08/2025
<b>Name of Provider or Supplier</b>  Andrew Chung Md, Pllc	<b>Street Address, City, State</b>  3600 Gaston Ave #755, Dallas, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced routine recertification survey of the laboratory was conducted on 07/08 /2025. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. Standard level deficiencies were cited.
<b>D5807</b>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy, a random review of patient test reports from June 2025, and staff interview, the laboratory failed to include its own reference intervals for 11 of 11 chemistry patient final reports. Findings include: 1. Review of the laboratory's policy titled "Evaluation of Automated Test Methods", approved by the laboratory director on 06/01/2021 stated: "Normal Ranges (Reference Intervals) ... 2. The results to these 20 samples will be used to validate the established reference intervals ... Summary ... This evaluation should be documented, and all worksheets, instrument printouts, and related documents shall be retained for the life of the method plus two years for regulatory inspection purposes." 2. A random review of patient final reports determined the laboratory failed to include its own reference intervals for 11 of 11 chemistry patient final reports: a. Accession ID: 213852X751920 Collection date: 06/09/2025 10:39:00 Received date: 06/09/2025 15:36:04 1. Analyte: Alanine Aminotransferase Laboratory policy range: 7 - 52 U/L Patient final report range: 0 - 40 U/L 2. Analyte: Aspartate Aminotransferase Laboratory policy range: 10 - 40 U/L Patient final report range: 0 - 40 U/L 3. Analyte: Alkaline Phosphatase Laboratory policy range: 40 - 130 U/L Patient final report range: 0 - 130 U/L 4. Analyte: Creatinine Laboratory policy range: 0.60 - 1.30 mg/dL Patient final report range: 0 -</p>

1.3 mg/dL 5. Analyte: Blood Urea Nitrogen Laboratory policy range: 9 - 20 mg/dL Patient final report range: 0 - 20 mg/dL b. Accession ID: 213852X811782 Collection date: 06/10/2025 07:41:00 Received date: 06/10/2025 15:21:08 1. Analyte: Alanine Aminotransferase Laboratory policy range: 7 - 52 U/L Patient final report range: 0 - 40 U/L 2. Analyte: Aspartate Aminotransferase Laboratory policy range: 10 - 40 U/L Patient final report range: 0 - 40 U/L 3. Analyte: Alkaline Phosphatase Laboratory policy range: 40 - 130 U/L Patient final report range: 0 - 130 U/L 4. Analyte: Creatinine Laboratory policy range: 0.60 - 1.30 mg/dL Patient final report range: 0 - 1.3 mg/dL 5. Analyte: Blood Urea Nitrogen Laboratory policy range: 9 - 20 mg/dL Patient final report range: 0 - 20 mg/dL c. Accession ID: 213852X845419 Collection date: 06/12/2025 07:51:00 Received date: 06/13/2025 13:03:07 1. Analyte: Alanine Aminotransferase Laboratory policy range: 7 - 52 U/L Patient final report range: 0 - 40 U/L 2. Analyte: Aspartate Aminotransferase Laboratory policy range: 10 - 40 U/L Patient final report range: 0 - 40 U/L 3. Analyte: Alkaline Phosphatase Laboratory policy range: 40 - 130 U/L Patient final report range: 0 - 130 U/L 4. Analyte: Creatinine Laboratory policy range: 0.60 - 1.30 mg/dL Patient final report range: 0 - 1.3 mg/dL 5. Analyte: Blood Urea Nitrogen Laboratory policy range: 9 - 20 mg/dL Patient final report range: 0 - 20 mg/dL d. Accession ID: 213852X846713 Collection date: 06/12/2025 10:37:00 Received date: 06/12/2025 15:00:05 1. Analyte: Alanine Aminotransferase Laboratory policy range: 7 - 52 U/L Patient final report range: 0 - 40 U/L 2. Analyte: Aspartate Aminotransferase Laboratory policy range: 10 - 40 U/L Patient final report range: 0 - 40 U/L 3. Analyte: Alkaline Phosphatase Laboratory policy range: 40 - 130 U/L Patient final report range: 0 - 130 U/L 4. Analyte: Creatinine Laboratory policy range: 0.60 - 1.30 mg/dL Patient final report range: 0 - 1.3 mg/dL 5. Analyte: Blood Urea Nitrogen Laboratory policy range: 9 - 20 mg/dL Patient final report range: 0 - 20 mg/dL e. Accession ID: 213852X806482 Collection date: 06/19/2025 07:43:00 Received date: 06/23/2025 15:42:05 1. Analyte: Alanine Aminotransferase Laboratory policy range: 7 - 52 U/L Patient final report range: 0 - 40 U/L 2. Analyte: Aspartate Aminotransferase Laboratory policy range: 10 - 40 U/L Patient final report range: 0 - 40 U/L 3. Analyte: Alkaline Phosphatase Laboratory policy range: 40 - 130 U/L Patient final report range: 0 - 130 U/L 4. Analyte: Creatinine Laboratory policy range: 0.60 - 1.30 mg/dL Patient final report range: 0 - 1.3 mg/dL 5. Analyte: Blood Urea Nitrogen Laboratory policy range: 9 - 20 mg/dL Patient final report range: 0 - 20 mg/dL f. Accession ID: 213852X848410 Collection date: 06/19/2025 09:39:00 Received date: 06/23/2025 15:45:19 1. Analyte: Alanine Aminotransferase Laboratory policy range: 7 - 52 U/L Patient final report range: 0 - 40 U/L 2. Analyte: Aspartate Aminotransferase Laboratory policy range: 10 - 40 U/L Patient final report range: 0 - 40 U/L 3. Analyte: Alkaline Phosphatase Laboratory policy range: 40 - 130 U/L Patient final report range: 0 - 130 U/L 4. Analyte: Creatinine Laboratory policy range: 0.60 - 1.30 mg/dL Patient final report range: 0 - 1.3 mg/dL 5. Analyte: Blood Urea Nitrogen Laboratory policy range: 9 - 20 mg/dL Patient final report range: 0 - 20 mg/dL g. Accession ID: 213852X825084 Collection date: 06/23/2025 08:34:00 Received date: 06/23/2025 16:12:12 1. Analyte: Alanine Aminotransferase Laboratory policy range: 7 - 52 U/L Patient final report range: 0 - 40 U/L 2. Analyte: Aspartate Aminotransferase Laboratory policy range: 10 - 40 U/L Patient final report range: 0 - 40 U/L 3. Analyte: Alkaline Phosphatase Laboratory policy range: 40 - 130 U/L Patient final report range: 0 - 130 U/L 4. Analyte: Creatinine Laboratory policy range: 0.60 - 1.30 mg/dL Patient final report range: 0 - 1.3 mg/dL 5. Analyte: Blood Urea Nitrogen Laboratory policy range: 9 - 20 mg/dL Patient final report range: 0 - 20 mg/dL h. Accession ID: 213852X845558 Collection date: 06/24/2025 09:58:00 Received date: 06/25/2025 10:03:06 1. Analyte: Alanine Aminotransferase Laboratory policy range: 7 - 52 U/L Patient final report range: 0 - 40 U/L 2. Analyte: Aspartate Aminotransferase Laboratory policy range: 10 - 40 U/L

Patient final report range: 0 - 40 U/L 3. Analyte: Alkaline Phosphatase Laboratory policy range: 40 - 130 U/L Patient final report range: 0 - 130 U/L 4. Analyte: Creatinine Laboratory policy range: 0.60 - 1.30 mg/dL Patient final report range: 0 - 1.3 mg/dL 5. Analyte: Blood Urea Nitrogen Laboratory policy range: 9 - 20 mg/dL Patient final report range: 0 - 20 mg/dL i. Accession ID: 213852X812668 Collection date: 06/23/2025 12:45:00 Received date: 06/23/2025: 16:15:08 1. Analyte: Alanine Aminotransferase Laboratory policy range: 7 - 52 U/L Patient final report range: 0 - 40 U/L 2. Analyte: Aspartate Aminotransferase Laboratory policy range: 10 - 40 U/L Patient final report range: 0 - 40 U/L 3. Analyte: Alkaline Phosphatase Laboratory policy range: 40 - 130 U/L Patient final report range: 0 - 130 U/L 4. Analyte: Creatinine Laboratory policy range: 0.60 - 1.30 mg/dL Patient final report range: 0 - 1.3 mg/dL 5. Analyte: Blood Urea Nitrogen Laboratory policy range: 9 - 20 mg/dL Patient final report range: 0 - 20 mg/dL j. Accession ID: 213852X771731 Collection date: 06/25/2025 08:34:00 Received date: 06/25/2025 16:06:02 1. Analyte: Alanine Aminotransferase Laboratory policy range: 7 - 52 U/L Patient final report range: 0 - 40 U/L 2. Analyte: Aspartate Aminotransferase Laboratory policy range: 10 - 40 U/L Patient final report range: 0 - 40 U/L 3. Analyte: Alkaline Phosphatase Laboratory policy range: 40 - 130 U/L Patient final report range: 0 - 130 U/L 4. Analyte: Creatinine Laboratory policy range: 0.60 - 1.30 mg/dL Patient final report range: 0 - 1.3 mg/dL 5. Analyte: Blood Urea Nitrogen Laboratory policy range: 9 - 20 mg/dL Patient final report range: 0 - 20 mg/dL k. Accession ID: 213852X840359 Collection date: 06/26/2025 08:55:00 Received date: 06/26/2025 13:48:05 1. Analyte: Alanine Aminotransferase Laboratory policy range: 7 - 52 U/L Patient final report range: 0 - 40 U/L 2. Analyte: Aspartate Aminotransferase Laboratory policy range: 10 - 40 U/L Patient final report range: 0 - 40 U/L 3. Analyte: Alkaline Phosphatase Laboratory policy range: 40 - 130 U/L Patient final report range: 0 - 130 U/L 4. Analyte: Creatinine Laboratory policy range: 0.60 - 1.30 mg/dL Patient final report range: 0 - 1.3 mg/dL 5. Analyte: Blood Urea Nitrogen Laboratory policy range: 9 - 20 mg/dL Patient final report range: 0 - 20 mg/dL 3. The technical consultant (as listed on the CMS-209 form) confirmed the findings in an interview conducted on 07/08/2025 at 1400 hours in the office. Key: U/L - Units per liter mg/dL - milligrams per deciliter CMS - Centers for Medicare and Medicaid Services