Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0860102	06/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ibr Specialty Clinical Laboratories	1050 Forest Hill Road, Staten Island, NY	

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	A federal surveyor from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted an announced CLIA Exempt State validation survey at IBR SPECIALTY CLINICAL LABORATORIES on June 25, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to not be in compliance with all condition-level CLIA requirements. The following condition and standard-level deficiencies were found during CLIA exempt-state validation survey performed on June 25, 2024.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of internal Proficiency Testing (PT) records and interview with the laboratory director (LD), the laboratory failed to have testing personnel (TP) sign the attestation forms attesting that PT samples were tested in the same manner as patient specimens for four of four Fragile X PT event from June 2022 to June 2024. Findings Include: 1. Review of the laboratory's internal Fragile X PT records from June 2022 to June 2024 revealed, the TP performing PT events in 2022, 2023 and 2024 did not sign four of four attestation forms to attest that PT samples were tested in the same manner as patient specimens: 2022 - 1 of 1 event 2023 - 2 of 2 events 2024 - 1 of 1 event 2. Interview with the LD confirmed the TP did not attest to PT performed from June 2022 to June 2024 on June 25, 2024 at 12:45 pm.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)

	The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of laboratory's written policy and procedures, lack of received specimen documentation, and interview with laboratory director (LD), the laboratory failed to document the temperature for received fragile X specimens received from 2022 to 2024. Findings Include: 1. The Fragile X testing procedure under Section A - General procedures and Polices, 1. specimen collection a. whole blood states, "in purple (EDTA) yellow or green top tubes obtained by ventiputure tube should be labeled with patient name and date drawn. Samples can be shipped at ambient temperature or shipped on cold pack 4 degrees Celsius". 2. On June 25, 2024 at 11:00 am, the laboratory was unable to provide documented specimen received temperatures for fragile X testing specimen received by the laboratory from June 2022 to June 2024. 3. Per the CMS 116 signed by the LD on June 20, 2024, the laboratory's total estimated annual test volume is 504 for fragile X testing. 4. Interview with the LD on May June 25, 2024 at 12:45 pm, confirmed the findings above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature records and interview with the laboratory director (LD), the laboratory failed to establish laboratory room temperature reference ranges and humidity ranges for where one of one Appliedbiossytems (ABS) 3500/3500xL Genetic Analyzer is used to perform fragile X testing from June 2022 to June 2024. Findings Include: 1. The ABS 3500/3500xL Genetic Analyzer USER GUIDE, table 13 Environmental requirements (continued), page 317 states, "Operating Conditions 15-30C (59-86F) (Room temperature should not fluctuate 2C during an instrument run) 20-80% relative humidity, noncondensing". 2. Review of the laboratory temperature records on June 25, 2024 at 12:00 pm revealed, the records did not include established temperature and humidity ranges in the laboratory where clinical testing was performed (room three). 3. One of one ABS genetic analyzer was kept in room three for fragile X testing from June 2022 to June 2024. 4. Per the CMS 116 signed by the LD on June 20, 2024, the laboratory's total estimated annual test volume is 504 for fragile X testing. 5. Interview with the LD on June 25, 2024 at 12:45 pm, confirmed the findings above.
D6076	LABORATORY DIRECTOR

	CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Laboratory Director (LD) educational credentials and interview with the LD and the Administrator of Specialty Clinical Laboratories, the LD failed to meet the qualification requirements of 493.1443 from June, 2022 to June 2024. Findings Include: 1. Refer to D6078.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on review of the Laboratory Director (LD) educational credentials and interview with the LD and the Administrator of Specialty Clinical Laboratories, the LD failed to meet qualification requirements of 493.1443 from June 2022 to June

	2024. Findings Include: 1. Review of the LD's educational qualifications on June 25, 2024 at 9:30 am revealed, the LD completed PhD in Biology, but was unable to provide documentation of an approved board certification that qualify them to be a high complexity laboratory director. 2. Per the CMS 116 signed by the LD on June 20, 2024 the laboratory's estimated annual test volume was 504. 3. Interview with the LD June 25, 2024 at 12:45 pm, confirmed the findings above.