

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2109338	(X3) Date Survey Completed 09/17/2026
Name of Provider or Supplier First Baptist Medical Center	Street Address, City, State 8111 Meadow Road, Dallas, 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	The laboratory was surveyed on 09/15-09/17/2026 in response to complaint TX00565162 for compliance with CMS 42CFR regulations. The facility was found to be out of compliance with CLIA regulations 42 CFR Part 493. CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.1441 Laboratory Director, high complexity Complaint TX00565162 was substantiated.
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 laboratory director's separation letter, laboratory test volume records, blood utilization records, and confirmed in interview, the laboratory failed to employ 1 of 1 qualified laboratory director overseeing high complexity testing from August 1, 2026-the exit date of the survey, September 17, 2026. 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 (b)(2)(i) 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)(ii) Have at least 2 years of experience directing or supervising high complexity testing; and (b)(2)(iii) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(3)(ii) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(iii) Have at least 2 years of: (b)(3)(iii)(A) Laboratory training or experience, or both; and (b)(3)(iii)(B) Laboratory experience directing or supervising high complexity testing; and (b)(3)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of high complexity testing under this section if they were qualified and serving as a laboratory director of high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(5) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology.

This STANDARD is not met as evidenced by:

Based on laboratory director's separation letter, laboratory test volume records, blood utilization records, and confirmed in interview, the laboratory failed to employ 1 of 1 qualified laboratory director overseeing high complexity testing from August 1, 2026- the date of the survey. Findings included: 1. Review of the laboratory director's separation letter dated August 10, 2026, that was submitted to Texas Health and Human Services stated: "I am writing to formally notify Texas Health and Human Services of my separation from First Baptist Medical Center (dba St Raphael Health Dallas), 8111 Meadow Road, Dallas, Texas, effective August 1, 2026. This separation ends my contractual relationship as Medical Director at First Baptist Medical Center (dba St Raphael Health Dallas), CLIA ID 45D2109338. This notification is provided in accordance with applicable Texas Health and Human Services requirements to ensure accurate provider records and compliance with CLIA guidelines. Please update your records to reflect this change and remove any association between my name, [XX], MD (NPI [XX]), and First Baptist Medical Center (dba St. Raphael Health Dallas) (NPI [XX]) effective on the date noted above." 2. Review of the laboratory's test volume records from August 1, 2026, to August 31, 2026, listed at test count of 1909 tests performed, that included 20 ABO/Rh and 10 antibody screens. 3. Review of the laboratory's blood utilization records for August 2026 listed 3 units of PRBC's transfused and 2 units of platelets transfused. 4. During an interview on August 15, 2026, at 9:55 AM, the laboratory supervisor was asked the name of the current laboratory director. She stated that the corporate office was trying to find a replacement laboratory director because they did not have one. During an interview on August 15, 2026, at 10:00 AM, the chief nursing officer stated that the laboratory was transitioning from a takeover and was hiring a laboratory director. During an

interview on August 15, 2026, at 11:55 AM, the laboratory supervisor stated the laboratory director resigned in August 2026. During an interview on August 17, 2026, at 11:25 AM, the chief executive officer stated that the laboratory did not secure the contract to rehire the laboratory director who had resigned from his directorship. He stated that he was awaiting the response of another pathologist to take the laboratory director's role but would not know until later that afternoon if she would accept the position. The above statements confirmed that the laboratory failed to employ 1 of 1 qualified laboratory director overseeing high complexity testing from August 1, 2026- the exit date of the survey, September 17, 2026. Word Key: dba - doing business as CLIA - Clinical Laboratory Improvement Amendment MD - medical doctor NPI - National Provider Identification St. - Saint PRBC's - packed red blood cells