Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0099572	02/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Bridgeport Hospital Laboratory	267 Grant St, Bridgeport, CT	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 record review and telephone staff interview, the laboratory failed to test proficiency testing (PT) samples in the same manner as patient samples in the subspecialty of Mycobacteriology. Findings include: 1. Record review on 2/15/2024 of the laboratory's PT evaluation report from the College of American Pathologists revealed the following survey with an unacceptable result for Acid Fast Bacilli (AFB) smear and Mycobacteria Screen: Year/Event Sample ID Grade/Score 2023/E1-B E1-07 Unacceptable. 2. Record review on 2/29/2024 of the laboratory's 'BH AFB cultures on the Versatrek ESP system' procedure manual for "Handling of AR negative Flagged Bottles" revealed the following: a. "Incubate the bottle in the AFB incubator and check for turbidity at least 2 times per week until the culture has been incubated a total of 35 days." b. "At 35 days, repeat AR staining prior to reporting." 3. Record review on 2/29/2024 of the laboratory's Beaker electronic work up documentation revealed the lack of documentation of a complete work up performed including the preliminary findings for the PT sample E1-07 for twice a week for 35 days. 4. Telephone interview on 2/29/2024 at 1:30 PM with the microbiology general supervisor (MGS) confirmed: a. The laboratory failed to follow the 'BH AFB cultures on the Versatrek ESP system' procedure as listed in 2a and 2b above. b. The MGS

	further commented that PT samples workup was noted on the sample bottle itself but if this was a patient, there would have been a paper trail of the workup documentation. 5. The laboratory performs 870 AFB tests annually in the subspeciality of Mycobacteriology.
D2035	MYCOBACTERIOLOGY CFR(s): 493.825(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to properly investigate and take remedial action when unacceptable Proficiency Testing (PT) results were obtained in the subspecialty of Mycobacteriology. Findings include: 1. Record review on 2/15/2024 of the laboratory's PT evaluation report from the College of American Pathologists revealed the following survey with an unacceptable result for Acid Fast Bacilli (AFB) smear and Mycobacteria Screen: Year/Event Sample ID Grade/Score 2023/E1-B E1-07 Unacceptable. 2. Record review on 2/15/2024 of the laboratory's 'Qualitative Laboratory Result-CAP Survey Action Report' revealed the following corrective action(s) were taken: a. "Investigation: Expected Response: Positive Smear and Positive Culture". "Our Response: Negative Smear and Negative Culture". b. "Was there a clerical error - No" c. "Could patient care have been affected - No" d. "Action Taken: Extra slide AR stained and ESP bottle slide made and AR stained. No organism seen. LJ slant has growth and was stained. Stain was positive from LJ slant." Note: Lack of documentation for a thorough investigation for the unacceptable PT score and/or remedial action to prevent reoccurrence. 3. Staff interview on 2/15/2024 at 2:45 PM with Laboratory Director confirmed the above findings. 4. The laboratory performs 870 AFB tests annually in the subspeciality of Mycobacteriology.