

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1025855	(X3) Date Survey Completed 03/15/2021
Name of Provider or Supplier Pillow Clinic P L L C	Street Address, City, State 101 Shirley Hicks Drive, Helena, AR	
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 is in compliance with CFR 493/41, reporting of Covid-19 results.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's package insert, review of quality control records, review of Covid-19 test log book, lack of documentation and interview with laboratory staff members it was determined that the laboratory failed to follow manufacturer's instructions for the performance of external quality control for each new lot number and each new operator for five of six testing personnel. Survey findings follow: A. Review of the manufacturer's package insert for the BD Veritor Covid 19 Antigen test kit showed that external positive and negative quality control is recommended to be performed for "each new kit lot" and for "each new operator." B. Review of the laboratory's record of external quality control results showed that external quality control was performed for each lot number of test kits and all external control was performed by the laboratory staff member identified as number six on the separate testing personnel identification list. C. In an interview on 3/15/21 at 12:10 PM the laboratory staff member, identified as number six on the separate testing personnel identification list, said that she performs external quality control on all new lots of BD Veritor Covid-19 test kits upon receipt and that she is the only staff member who performs external quality control on those test kits. D. Review of the test log for Covid-19 antigen testing for the calendar year of 2021 showed that six testing personnel, identified as numbers one through six on the separate testing personnel identification list, performed Covid-19 antigen using the BD Veritor test system. E. Upon request, the laboratory was unable to provide documentation of external quality</p>

control being performed by testing personnel identified as numbers one through five on the separate testing personnel identification list. F. In an interview on 3/15/21 at 12:30 PM, laboratory staff member identified as number six on the separate testing personnel identification list, confirmed that the personnel, identified as numbers one through five on the separate testing personnel identification list, had not performed external quality control for the BD Veritor Covid-19 test kits at any time.