Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1064019	02/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Danville Patient Care, Inc	1955 Memorial Drive, Danville, VA	

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	An announced CLIA recertification survey was conducted at Danville Patient Care, Inc. on February 1, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of job duties, quality assessment policy (QA), testing personnel (TP) competency assessment records, and an interview, the laboratory failed to assess competency for the technical consultant (TC) in 2016 and 2017. Findings include: 1. Review of the TC job duties revealed that the TC was assigned duties in September 2014. 2. Review of the QA policy defines the TC as part of the laboratory personnel. The QA policy states that "Laboratory employees will have training and competency assessments performed twice during their first year, annually and as needed thereafter. Training and competency assessment are maintained as part of each employee's personnel file." 3. Review of TP competency assessment records revealed no documentation of an annual competency assessment for the TC in 2016 and 2017. The inspectors requested competency documentation for the TC. No documentation was available for review. 4. An interview with the TC at approximately 10:30 AM confirmed that the laboratory failed to assess competency for the TC for 2016 and 2017 as defined within the QA policy.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d)

	Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the policy manual and an interview, the laboratory director failed to approve the Qualigen FastPack IP system placed into use on February 7, 2017. Findings include: 1. Review of the policy manual revealed a procedure for the Qualigen FastPack IP system for the testing of vitamin D and Thyroid Stimulating Hormone (TSH) analytes. The Qualigen FastPack IP system was placed into use on February 7, 2017. The procedure was not signed and approved by the laboratory director. 2. An interview with the technical consultant at approximately 11:00 AM confirmed that the laboratory director failed to sign and approve the procedure for the Qualigen test system.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of initial verification studies and an interview, the laboratory director failed to review and approve initial verification studies for a new instrument placed into use on February 7, 2017. Findings include: 1. Review of the initial verification studies for the Qualigen FastPack IP system for the testing of vitamin D and Thyroid Stimulating Hormone (TSH) analytes revealed that the verification studies were completed on February 7, 2017. There was no evidence of review and approval of the initial verification studies by the laboratory director. 2. An interview with the technical consultant at approximately 11:00 AM confirmed that the laboratory director failed to review and approve the initial verification studies for the Qualigen system for testing vitamin D and TSH.