Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2004621	03/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Opans, Llc	4134 Alston Avenue, Suite 100, Durham, NC	

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
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of random patient test reports, and interview with the director on 3/7/18, the laboratory director failed to ensure that the laboratory's PSA (Prostatic Specific Antigen) and Free PSA (Prostatic Specific Antigen) test reports included the identity of the assay used. Findings: 1. The laboratory performs Prostatic Specific Antigen (PSA) testing using the IMMULITE 2000 PSA solid-phase, chemiluminescence immunometric assay. The manufacturer's product insert (PIL2KPTSD-2, 2014-01-16) for this test reads in the section entitled, "Caution: ...The concentration of PSA in a given specimen determined with different assays can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the assay used...". 2. The laboratory performs Free Prostatic Specific Antigen (PSA) testing using the IMMULITE 2000 Free PSA solid-phase, sequential chemiluminescence immunometric assay. The manufacturer's product insert (PIL2KPFD-27, 2015-04-20) for this test reads in the boxed section, "...The concentration of Free PSA in a given specimen determined with different assays can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the assay used...". 3. Review of a random computer generated patient reports for PSA (#17000201751); and, PSA - free (#2018014001) revealed that the test reports did not include the

	method used for PSA or Free PSA. 4. During interview at approximately 10:15 a.m., the laboratory director confirmed that the PSA and Free PSA methods were not included in te patient test reports reported to the physicians.