Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0337479	02/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Robert Brody Md, Co	3461 Warrensville Ctr Rd Ste 101, Shaker Heights, OH	

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
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to document hematoxylin and eosin (H & E) quality control (QC) procedures for the intended stain reactivity to ensure predictable staining characteristics each day of use. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any mention of the criteria of acceptability of the intended H & E stain reactivity. 2. Review of four out of four of the laboratory's 2016 and 2017 H & E records documented for each tissue biopsy test report in each patient chart, provided on the date of the inspection and reviewed, found indication of slide QC with "Satisfactory" recorded. The laboratory did not include a legend defining "Satisfactory" and did not include the intended staining characteristics of the H & E stains in their policies and procedures. 3. The Laboratory Director confirmed the laboratory did not include established criteria for the intended stain reactivity of the H & E stain in their policies and procedures and did not document the actual observed H & E staining characteristics each day of patient testing. The interview occurred on 02/21/2018 at 11:15 AM.