

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001051	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 01/10/2012
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NAME OF PROVIDER OR SUPPLIER INDIANAPOLIS ENDOSCOPY CENTER LLP	STREET ADDRESS, CITY, STATE, ZIP CODE 8315 E 56TH ST STE 100 INDIANAPOLIS, IN 46216
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S0000	<p>This visit was for a State licensure survey.</p> <p>Facility Number: 007886</p> <p>Survey Date: 1-9/10-12</p> <p>Surveyors: Jack I. Cohen, MHA Medical Surveyor</p> <p>Deborah Franco, RN Public Health Nurse Surveyor</p> <p>QA: claughlin 01/13/12</p>	S0000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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S0450	<p>410 IAC 15-2.5-1(g)</p> <p>(g) Sterilization of equipment and supplies must be provided, within the scope of the service offered, in accordance with acceptable standards of practice or manufacturer's recommendations and applicable state laws and rules, 410 IAC 1-4. Sterilization services must be directed by a qualified person or persons and must provide for the following:</p> <p>Based on observation, policy review, document review, and interview, the facility failed to assure biological indicators were correctly used to check sterilization for one (1) of one (1) steam autoclaves inspected.</p> <p>Findings include:</p> <ol style="list-style-type: none"> On 1-9-2012 at 10:30 AM, during tour of the facility and in the presence of S1 and S2, the biological log for the steam autoclave was observed to contain >30 entries in which an 3M Attest biological indicator (BI) had been processed and incubated for steam autoclave cycle without a control biological indicator documented that day. Facility policy "Autoclave" last reviewed/revised 5/12/2011, on page 2, 13, a, states "Biological indicators will be used for monitoring the mechanical 	S0450	<p>A QA study was initiated 1/16/2012 addressing the inconsistency of technicians in documenting and using biological control indicators as specified in the manufacturers instructions. Retraining of technicians took place on 1/16/2012 and compentancy in using and documentation of biological indicators, including the control indicators, was reviewed and assessed again on 2/7/2012. Records of compentancy are on file at the facility. The biological indicator/control log form was revised to clarify the biological control documentation. The compentancy training content was clarified to insure proper use of control indicators. Annually compentancy on the use of the autoclave, including biological indicator and control use and documentation will be addressed and documented annually. This will be the repsonsibility of the infection control officer.</p>	01/16/2012			

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	<p>function and operator's technique of the autoclave sterilizer" and "Biological test monitoring is to be done with every load, or at least weekly and documented in the Biological Log"and "Follow manufacturer's directions for proper utilization of the biological indicator".</p> <p>3. Manufacturer's instructions for Attest biological indicators and incubator states under use "Use of Positive Controls" that: "The use of positive controls is required to ensure correct incubation conditions, viability of spores and capability of the medium to promote growth. A non-sterilized 3M Attest biological indicator from the the same lot should be used in each incubator each day biological indicators are used as a positive growth control....a yellow colour in the control vial demonstrates correct incubation, viability of spores and capability of the medium to promote rapid growth....Record results in the record keeping log book".</p> <p>4. During interview with P6 on 1-10-2012 at 11:49 AM, P6 indicated that:</p> <p>a. P6 is an Instrument Room Technician and is predominantly responsible for operation, cleaning, and maintenance of the autoclave and the biological indicators, incubator, and logs.</p>				

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	<p>b. the facility uses 3M Attest BI's and incubator.</p> <p>b. BI (spore test) is performed once a week that autoclave loads are processed.</p> <p>c. that P6 places a BI in the center of the load prior to processing, cools the load for 10 minutes after processing, then removes the BI, crushes it in the 3M Attest incubaor, monitors the BI, and then records the final result at 48 hours.</p> <p>d. P6 does not crush and incubate an unprocessed BI for each autoclave load run (per manufacturer's recommendations) or weekly (per facility policy).</p> <p>5. During interview with S2 on 1-10-2012 at 12:05 PM, S2 stated:</p> <p>a. that S2 is the Infection Control Preventionist for the facility and is responsible for assurance of compliance with manufacturer's recommendations for assurance of sterility of steam autoclaved items.</p> <p>b. that the BI log lacked documentation of a control BI performed each day an autoclave load was processed.</p> <p>c. that manufacturer's recommendation requires the use of a positive control for each incubator each day BI's are used but that faciltly policy minimum requirement is for weekly use of BI.</p> <p>d. verified the above findings and</p>						

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	confirmed that the facility has not followed manufacturer's recommendations for use of a positive control BI each day for which an autoclave cycle is processed to sterilize items.			
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