

# INDEPENDENT DIAGNOSTIC TESTING FACILITIES—SITE INVESTIGATION

## 42 CFR § 410.33

Date Ordered: \_\_\_\_\_

Date of First Visit: \_\_\_\_\_

Time: \_\_\_\_\_

Date of Second Visit: \_\_\_\_\_

Time: \_\_\_\_\_

### 1. REASON FOR VISIT

Initial/Change       Revalidation       Hearing & Appeal       Ad Hoc

### 2. FACILITY INFORMATION

Facility Name		National Provider Identifier (NPI)	
Name of Authorized Representative(s) or Interviewee(s)		Name of Authorized Representative(s) or Interviewee(s)	
Name of Authorized Representative(s) or Interviewee(s)		Name of Authorized Representative(s) or Interviewee(s)	
Practice Location ( <i>Physical Street Address</i> )			
City	State	Zip Code	Business Telephone Number

### 3. FACILITY INSPECTION

#### A. PERFORMANCE STANDARD #3

**Performance Standard #3** requires IDTFs to maintain a physical facility on an appropriate site.  
**(PHOTOGRAPH REQUIRED)**

Office Suite-Mall       Office Suite-Office Building       Private Residence       Warehouse  
 Other. Please describe: \_\_\_\_\_

1. Is the IDTF located on an appropriate site?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
If <b>NO</b> , describe: _____			
2. Is the IDTF handicap accessible?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
If <b>NO</b> , describe: _____			
3. Were there patients in the facility during the inspection?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
If <b>NO</b> , describe: _____			
4. If this IDTF is at a fixed location, does the facility contain adequate space for testing, including all tests listed on the enrollment application, facilities for hand washing, adequate patient privacy accommodations, and storage of business and medical records?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
If <b>NO</b> , describe: _____			
5. If this IDTF is a mobile facility, does the mobile unit have access to facilities for hand washing, adequate patient privacy accommodations, and a home office location for the storage of business and medical records?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
If <b>NO</b> , describe: _____			

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**B. PERFORMANCE STANDARD #4**

**Performance Standard #4** requires IDTFs to have all applicable diagnostic testing equipment available at the physical site (excluding portable diagnostic testing equipment).

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1. Does the IDTF maintain a catalog of portable diagnostic equipment, including diagnostic testing equipment serial/registration numbers, at the physical site?  Yes  No  N/A

If **NO**, describe: \_\_\_\_\_

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2. Did the IDTF make the portable equipment or mobile unit(s) available for inspection?  Yes  No  N/A

If **NO**, describe: \_\_\_\_\_

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3. Does the IDTF maintain a current inventory of diagnostic equipment, including diagnostic testing equipment serial/registration numbers?  Yes  No

If **NO**, describe: \_\_\_\_\_

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4. Has the IDTF provided updates to the MACs regarding equipment changes in accordance with existing regulation?  Yes  No

If **NO**, describe: \_\_\_\_\_

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**C. PERFORMANCE STANDARD #5**

**Performance Standard #5** requires IDTFs to maintain a primary business phone under the name of the business.

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1. Is the business telephone located at the IDTF or within the home office for the mobile IDTF?  Yes  No

If **NO**, describe: \_\_\_\_\_

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2. Is the business telephone number listed in local telephone directory or is it available through directory assistance?  Yes  No

If **NO**, describe: \_\_\_\_\_

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**D. PERFORMANCE STANDARD #6**

**Performance Standard #6** requires IDTFs to have comprehensive liability insurance in the amount \$300,000 per facility.

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1. Did the IDTF provide proof of insurance upon request?  Yes  No

If **NO**, describe: \_\_\_\_\_

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**E. PERFORMANCE STANDARD #7**

**Performance Standard #7** states that IDTFs must agree not to directly solicit patients; this includes, but is not limited to, a prohibition on telephone, computer, or in-person contacts.

How does the IDTF solicit new business? Describe:

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**F. PERFORMANCE STANDARD #8**

**Performance Standard #8** requires IDTFs to maintain a protocol regarding beneficiaries' complaints.

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1. Does the supplier have a written complaint resolution procedure established?  Yes  No

If **NO**, describe: \_\_\_\_\_

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**G. PERFORMANCE STANDARD #9**

**Performance Standard #9** requires IDTFs to post these standards for beneficiary review.

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1. Has the IDTF posted the standards found at 42 CFR § 410.33 in the IDTF or home office for a mobile IDTF?  Yes  No
- If NO, describe: \_\_\_\_\_
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**H. PERFORMANCE STANDARD #11**

**Performance Standard #11** requires IDTFs to have their diagnostic equipment calibrated and maintained per manufacturer's equipment instructions and in compliance with applicable manufacturer's suggested maintenance and calibration standards.

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1. Does the IDTF have proof that diagnostic equipment has been calibrated and maintained per equipment instructions in accordance with manufacturer's instructions?  Yes  No
- If NO, describe: \_\_\_\_\_
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2. Did the IDTF provide a copy of the maintenance log upon request?  Yes  No
- If NO, describe: \_\_\_\_\_
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**I. PERFORMANCE STANDARD #12**

**Performance Standard #12** requires IDTFs to have technical staff on duty with the appropriate credentials to perform the tests.

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1. Can the IDTF furnish the applicable Federal/State licenses and/or certifications for the individuals performing these services?  Yes  No
- If NO, describe: \_\_\_\_\_
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2. Can technical staff identify the supervising physician(s)?  Yes  No
- If YES, list name(s) of supervising physician(s) that was provided by the technician. \_\_\_\_\_
- If NO, describe: \_\_\_\_\_
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3. Is the supervising physicians(s) on site?  Yes  No
- If NO, describe: \_\_\_\_\_
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4. Did the IDTF provide a written list of the technician(s) that will be furnishing services at this IDTF upon request?  Yes  No
- If NO, describe: \_\_\_\_\_
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5. Did the IDTF provide a written list of the supervising physician(s) that will be supervising services at this IDTF upon request?  Yes  No
- If NO, describe: \_\_\_\_\_
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**J. PERFORMANCE STANDARD #13**

**Performance Standard #13** requires IDTFs to have proper medical record storage and be able to retrieve medical records upon request within 2 business days.

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1. Can the IDTF retrieve medical records within 2 business days?  Yes  No
- If NO, describe: \_\_\_\_\_
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2. Does the IDTF have proper medical records storage?  Yes  No
- If NO, describe: \_\_\_\_\_
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3. How are the records stored?
- On-site  Electronically  Storage Facility  Other: \_\_\_\_\_
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**K. PERFORMANCE STANDARD #14**

**Performance Standard #14** requires IDTFs to permit CMS or its Contractors to conduct unannounced on-site inspections to confirm the IDTF's compliance.

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1. Is the IDTF accessible during regular business hours?  Yes  No

If **NO**, describe: \_\_\_\_\_

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2. Does the facility maintain posted hours of operation?  Yes  No

a. If **YES**, list hours of operation below:

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

b. If **NO**, describe: \_\_\_\_\_

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**L. PERFORMANCE STANDARD #15**

**Performance Standard #15** states that with the exception of hospital-based and mobile IDTFs, a fixed-base IDTF is prohibited from the following:

- Sharing a practice location with another Medicare-enrolled individual or organization;
  - Leasing or subleasing its operations or its practice location to another Medicare-enrolled individual or organization; or
  - Sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.
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1. Does the IDTF share its practice location?  Yes  No

If **YES**, describe: \_\_\_\_\_

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2. Does the IDTF share diagnostic equipment?  Yes  No

If **YES**, describe: \_\_\_\_\_

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3. Does the IDTF lease or sublease its operation or its practice?  Yes  No

If **YES**, describe: \_\_\_\_\_

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#### 4. ADDITIONAL QUESTIONS FOR INSPECTOR

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A. Was the inspector able to complete the site visit?  Yes  No

If **NO**, describe: \_\_\_\_\_

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B. Additional Comments (if none, please check N/A)  N/A

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C. Beyond what is disclosed in this site visit worksheet, was there any evidence obtained during the site visit that could indicate that the supplier is not in compliance with the provisions in 42 CFR 410.33?  Yes  No

If **YES**, describe: \_\_\_\_\_

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#### D. Photographs Required

- Photograph exterior of building (including business sign & hours of operation if possible)
- Photograph interior facility entrance if located within a multiple tenant building (business signs & hours of operation, if possible)

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#### E. Inspector's Information and Signature

*I prepared this document, which is the report of my inspection of the noted facility pursuant to their enrollment in the Medicare program. This report is a true and accurate account of the events that occurred and transpired on the date(s) reported herein that this site visit was performed. I am capable and willing to testify as a witness at a hearing about the content of this report. The foregoing information is based on my personal knowledge or is information provided to me in my official capacity. I declare under penalty or perjury that this information is true and correct to the best of my knowledge and belief.*

Executed this \_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_

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Signature of Declarant

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Printed Name

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Organization

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