Form Approved
OMB No. 0938-1029
Expires: XX/XXXX

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

○ Fixed ○ Mobile ○ Indirect

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 *(Physical Street Address)*

City	State	Zip Code	Business Telephone Number

3. FACILITY INSPECTION

A. PERFORMANCE STANDARD 410.33(g)(3)

Performance Standard 410.33(g)(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? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A
2. Is the IDTF disability accessible? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A
3. Were there patients in the facility during the inspection? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A
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? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A
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? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A

B. PERFORMANCE STANDARD 410.33(g)(4)

Performance Standard 410.33(g)(4) requires IDTFs to have all applicable diagnostic testing equipment available at the physical site (excluding portable diagnostic testing equipment).

1. Does the IDTF maintain a catalog of portable diagnostic equipment, including diagnostic testing equipment serial/registration numbers, at the physical site? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A
2. Did the IDTF make the portable equipment or mobile unit(s) available for inspection? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A
3. Does the IDTF maintain a current inventory of diagnostic equipment, including diagnostic testing equipment serial/registration numbers? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A
4. Has the IDTF provided updates to the MACs regarding equipment changes in accordance with existing regulation? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A

C. PERFORMANCE STANDARD 410.33(g)(5)

Performance Standard 410.33(g)(5) requires IDTFs to maintain a primary business phone under the name of the business.

1. Is the business telephone located at the IDTF or within the home office for the mobile IDTF? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A
2. Is the business telephone number listed in local telephone directory or is it available through directory assistance? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A

D. PERFORMANCE STANDARD 410.33(g)(6)

Performance Standard 410.33(g)(6) requires IDTFs to have comprehensive liability insurance in the amount $300,000 per facility.

1. Did the IDTF provide proof of insurance upon request? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A

E. PERFORMANCE STANDARD 410.33(g)(7)

Performance Standard 410.33(g)(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:

F. PERFORMANCE STANDARD 410.33(g)(8)

Performance Standard 410.33(g)(8) requires IDTFs to maintain a protocol regarding beneficiaries' complaints.

1. Does the supplier have a written complaint resolution procedure established? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A

G. PERFORMANCE STANDARD 410.33(g)(9)

Performance Standard 410.33(g)(9). The IDTF must openly post the standards outlined in § 410.33(g) for review by patients and the public.

1. Has the IDTF posted the standards found at 42 CFR § 410.33 in the IDTF or home office for a mobile IDTF? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A

H. PERFORMANCE STANDARD 410.33(g)(11)

Performance Standard 410.33(g)(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.

1. Does the IDTF have proof that diagnostic equipment has been, self or manually, calibrated and maintained per equipment instructions in accordance with manufacturer's instructions? If **No or N/A**, describe (required): _____	○ Yes	○ No	○ N/A
2. Did the IDTF provide a copy of the maintenance log upon request? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A

I. PERFORMANCE STANDARD 410.33(g)(12)

Performance Standard 410.33(g)(12) requires IDTFs to have technical staff on duty with the appropriate credentials to perform the tests.

1. Can the IDTF furnish the applicable Federal/State licenses and/or certifications for the individuals performing these services? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A
2. Can technical staff identify the supervising physician(s)? If **Yes**, list name(s) of supervising physician(s) that was provided by the technician. _____ If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A
3. Is the supervising physician(s) identified by the technical staff on site? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A
4. Did the IDTF provide a written list of the technician(s) that will be furnishing services at this IDTF upon request? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A
5. Did the IDTF provide a written list of the supervising physician(s) that will be supervising services at this IDTF upon request? If **No or N/A**, describe: _____	○ Yes	○ No	○ N/A

J. PERFORMANCE STANDARD 410.33(g)(13)

Performance Standard 410.33(g)(13) requires IDTFs to have proper medical record storage and be able to retrieve medical records upon request within 2 business days.

1. Can the IDTF retrieve medical records within 2 business days? ○ Yes ○ No ○ N/A

   If **No or N/A**, describe: _____

2. Does the IDTF have proper medical records storage? ○ Yes ○ No ○ N/A

   If **No or N/A**, describe: _____

3. How are the records stored?

   ☐ On-site ☐ Electronically ☐ Storage Facility ☐ Other: _____

K. PERFORMANCE STANDARD 410.33(g)(14)

Performance Standard 410.33(g)(14) requires IDTFs to permit CMS or it's Contractors to conduct unannounced on-site inspections to confirm the IDTF's compliance.

1. Is the IDTF accessible during regular business hours? ○ Yes ○ No ○ N/A

   If **No or N/A**, describe: _____

2. Does the facility maintain posted hours of operation? ○ Yes ○ No ○ N/A

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

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

   b. If **No or N/A,** describe: _____

L. PERFORMANCE STANDARD 410.33(g)(15)

Performance Standard 410.33(g)(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.

1. Does the IDTF share its practice location? ○ Yes ○ No ○ N/A

   If **Yes**, describe: _____

2. Does the IDTF share diagnostic equipment? ○ Yes ○ No ○ N/A

   If **Yes**, describe: _____

3. Does the IDTF lease or sublease its operation or its practice? ○ Yes ○ No ○ N/A

   If **Yes**, describe: _____

4. ADDITIONAL QUESTIONS FOR INSPECTOR

a. Was the inspector able to complete the site visit? ○ Yes ○ No ○ N/A

If **No or N/A**, describe: _____

b. Additional Comments

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 ○ N/A

If **Yes**, describe: _____

d. Photographs Required

Refer to the contractor's statement of work.

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 _____

Signature of Declarant

Printed Name

Organization