

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
 ☐ Appeal
 ☐ Ad Hoc/Unannounced Visit

Facility Name: _____

Authorized Rep: _____ National Provider Identifier: _____

Practice Location (Physical Street Address): _____

City: _____ State: _____

Zip Code: _____ Business Telephone Number: _____

2. INSPECTIONWere you able to complete the site visit? ☐ Yes ☐ No

If unable to conduct site visit for any reason, explain below and stop.

Note: Performance Standard # 14 allows CMS/Contractors to conduct unannounced on-site inspections.

3. FACILITY INFORMATION**Performance Standard # 3** requires IDTFs to maintain a physical facility on an appropriate site.

☐ Office Suite-Mall
 ☐ Office Suite-Office Building
 ☐ Private Residence
 ☐ Warehouse

☐ Other. Please describe: _____

- | | |
|---|--|
| a. Is the IDTF located on an appropriate site? | ☐ Yes ☐ No |
| b. Is the IDTF handicap accessible? | ☐ Yes ☐ No |
| c. What is the approximate size of the supplier's facility? _____ | |
| d. Were there patients in the facility during the inspection? | ☐ Yes ☐ No |
| e. If a stationary IDTF, 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? | ☐ Yes ☐ No ☐ N/A |
| f. If 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? | ☐ Yes ☐ No ☐ N/A |

If "No", describe.

Performance Standard # 14 requires IDTFs to maintain a visible sign posting the normal business hours of the IDTF.

- a. Does the facility maintain posted hours of operation? ☐ Yes ☐ No
If yes, list hours of operation below:

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

4. FACILITY INFORMATION

Performance Standard # 4 requires IDTFs to have all applicable testing equipment available at the stationary site, excluding mobile IDTFs.

- a. Is applicable testing equipment available for inspection at the physical site or mobile vehicle? ☐ Yes ☐ No
 b. Does the IDTF maintain a diagnostic testing equipment catalog, including serial/registration numbers? ☐ Yes ☐ No
 c. Did the IDTF make the mobile equipment available for inspection within 2 business days? ☐ Yes ☐ No ☐ N/A
 d. Has the IDTF provided updates regarding equipment changes? ☐ Yes ☐ No

If "No", describe.

5. TELEPHONE & RECORDS

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

- a. Is the business telephone located at the IDTF or home office for a mobile IDTF? ☐ Yes ☐ No
 b. Is the business telephone number listed in local telephone directory or is it available through directory assistance? ☐ Yes ☐ No
 c. Is the business telephone number listed under the business name? ☐ Yes ☐ No

Confirmed by: ☐ White/Yellow Pages ☐ Viewed phone bill ☐ Directory Assistance

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

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

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

- a. 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", please describe.

6. COMPREHENSIVE LIABILITY INSURANCE

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

Request that the IDTF provide a copy of the insurance binder as well as the following information:

Name of Insurance Company: _____

Insurance Policy Number: _____

Date Policy Issued: _____ Expiration Date of Policy: _____

Insurance Agent's Name: _____

Insurance Agent's Telephone Number: _____ Fax Number: _____

Insurance Agent's E-Mail Address: _____

Underwriter's Agent's Name: _____

Underwriter's Agent's Telephone Number: _____ Fax Number: _____

Underwriter's E-Mail Address: _____

Is the insurance agent also the underwriter for this policy?

☐ Yes ☐ No

If yes, obtain written proof from the insurance company attesting that the agent is also the underwriter.

7. EQUIPMENT CALIBRATION

Performance Standard #11 requires IDTFs to calibrate diagnostic equipment in accordance with manufacturer's instructions.

a. Does the IDTF have proof that diagnostic equipment has been calibrated in accordance with manufacturer's instructions?

☐ Yes ☐ No

If "No", describe.

8. TECHNICAL STAFF

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

a. Can the IDTF furnish the applicable Federal/State licenses and/or certifications for the individuals performing these services?

☐ Yes ☐ No

b. Can technical staff identify the supervising physician that are listed in Attachment 2 of the CMS-855B?

☐ Yes ☐ No

c. Are the technician(s) listed on the CMS in Attachment 2 performing the test contained on the CMS-855B?

☐ Yes ☐ No

If "No", describe.

9. MEDICAL RECORDS

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

a. Can the IDTF furnish medical records?

☐ Yes ☐ No

If "No", describe.

10. ADDITIONAL COMMENTS

11. INSPECTOR INFORMATION AND SIGNATURE
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I certify that, to the best of my knowledge and belief, the responses on this worksheet accurately reflect the information that has been obtained during this site visit.

Printed Name of Site Visit Inspector

Date of Inspection

Signature of Site Visit Inspector

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-NEW**. The time required to complete this information collection is estimated to average **2 hours** per response, including the time to review instructions, search existing data resources, and gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

DRAFT