

Independent Diagnostic Testing Facility (IDTF)

An IDTF is a facility that is independent of and not associated with a doctor's office or hospital. This can include facilities that offer MRI screening, Mammogram, HIV testing, etc. IDTFs can be a fixed location or a mobile entity.



Scheduling the Site Visit

The goal of an IDTF SV at a Provider location is to verify that the facility meets the standards under 42 CFR § 410.33. The Inspector must document if the facility meets the qualifications.

An IDTF may be a fixed location, a mobile entity, or an individual, nonphysician practitioner. The facility must be open and operational at the time of the site visit. Because this site visit type requires a more in-depth interview, review of several documents, and additional photographs, IDTF site visits will take more time and interaction.

When you arrive to the facility, start by introducing yourself and asking for someone to assist with the site visit—this is usually an administrator, office manager, or billing associate.

“Hello, my name is John. I am here on behalf of the Centers for Medicare and Medicaid Services. Can I please speak with the office manager or person responsible for your application to participate as a Medicare provider/supplier?”

CMS has requested that I come to your office to conduct a site visit. I will need to look over some documentation and take a few pictures of the facility. I will do my best to not take up too much of your time.”

You will need to ask if the provider operates a mobile unit and request that the mobile unit be present to conduct the site visit.

Mobile IDTF

When visiting a mobile IDTF, inspectors are required to see the mobile unit in person.

Mobile units may be trailers, buses, or pop-up units, among other styles, and typically have an office or home base where it is stored when not in use. Services may or may not be conducted out of the home base.

Some site visit form questions pertain to the office or home base of the mobile unit.

- Review the SV form and answer the questions about the home base.
- Photograph the location including any required photos of applicable documentation or physical features.

Other questions directly relate to the mobile unit. Inspectors are expected to view and photograph some features of the mobile unit.

In some instances, inspectors may be asked to drive to a location where the mobile unit is operating in order to complete the site visit.



IDTF Performance Standards

We will now review the Performance Standards and questions that will be answered during the site visit.

- Performance Standards are defined by CMS for all providers to meet in order to qualify for participation with Medicare.
- Within each Performance Standard are a range of questions that must be answered to prove that the provider or supplier meets those standards.

The site visit form begins by asking you to fill in the full name and position of the person(s) that you speak with or who participate in the site visit.

Performance Standard	Question	Evaluation Explanation
Facility Information	Name of Authorized Representative(s) or Interviewee(s)	List the name and position of employee(s) interviewed during the SV.

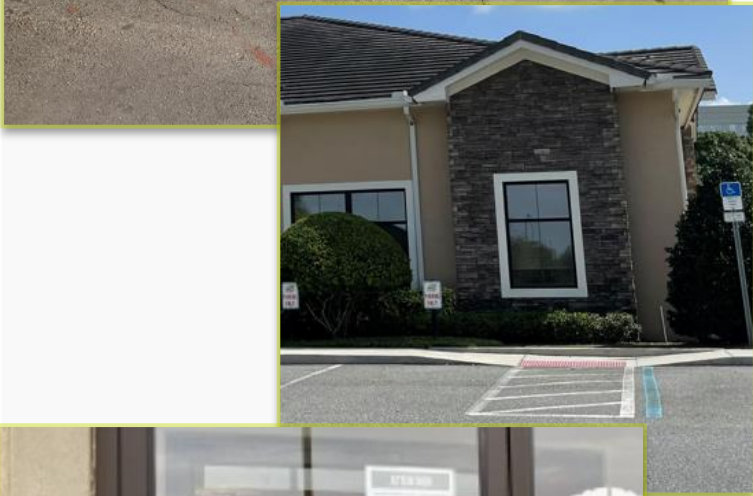
Performance Standard 3

Performance Standard	Question	Evaluation Explanation
Performance standard #3 requires IDTFs to maintain a physical facility on an appropriate site.	Type of facility <i>Photo required</i>	Determine the type of facility: • Office Suite-Mall – an office in an open-air shopping center where the stores are connected and arranged in a linear row, typically with a sidewalk in front • Office Suite-Office Building – an office in an enclosed, multi-tenant building with interior corridors and office entrance; may be of varying height • Select “Office Suite-Office Building” if provider is in a hospital or nursing home • Private Residence – any building, buildings, or part of a building owned by a private entity which serves as a permanent residence • Warehouse – a large building where raw materials or manufactured goods may be stored before distribution • Other – any building or facility type that does not meet any other type. An explanation is required



Performance Standard 3

Performance Standard	Question	Evaluation Explanation
Performance standard #3 requires IDTFs to maintain a physical facility on an appropriate site.	1. Is the IDTF located on an appropriate site? <i>Photo required</i>	The physical facility, including mobile units, must contain space for equipment appropriate to the services offered, facilities for hand washing, adequate patient privacy accommodations, and the storage of both business records and current medical records within the office setting of the IDTF, or IDTF home office (not within the actual mobile unit). A P.O. box, commercial mailbox, hotel, or motel is not an appropriate site. A mobile IDTF home office may be a Permanent Residence. This is acceptable if the mobile unit is present to be inspected.
	2. Is the IDTF handicap accessible? <i>Photo required</i>	If it is not accessible, ask and record how the provider accommodates disabled persons. Photograph how a person with a disability would enter the building from the outside. This may be a ramp, curb cutout, or level entrance. This is NOT a handicap parking space.
	3. Were there patients in the facility during the inspection?	Observe the activity in the facility to determine if patients are present.



Performance Standard 3

Performance Standard	Question	Evaluation Explanation
Performance standard #3 requires IDTFs to maintain a physical facility on an appropriate site.	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? <i>Photo required</i>	Review the offerings and photograph the facility to show what is available. • Answer “N/A” if visiting a mobile IDTF or home office of a mobile IDTF • Answer “Yes,” if ALL of the physical requirements are present • Answer “No,” if ANY of the physical requirements are not present Photos must include adequate space or lack thereof, facilities for handwashing, privacy accommodations (ability to close doors, privacy curtains), and storage of business records (a photo of a computer and explanation is required for electronic storage methods.) <i>Keep in mind that people should <u>never</u> be included in SV pictures. If a photo cannot be captured, please note the reason why in the “Additional Comments” section.</i>



Performance Standard 3

Performance Standard	Question	Evaluation Explanation
Performance standard #3 requires IDTFs to maintain a physical facility on an appropriate site.	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? <i>Photo required</i>	Review the offerings and photograph the facility to show what is available. • Answer “N/A” if visiting a fixed IDTF or home office of a mobile IDTF • Answer “Yes,” if ALL of the physical requirements are present • As mobile units have limited space, it is acceptable for these facilities/services to be mobile and moved into place when needed • Answer “No,” if ANY of the required facilities/services are missing Photos must include adequate space or lack thereof, facilities for handwashing, privacy accommodations (ability to close doors, privacy curtains), and storage of business records (a photo of a computer and explanation is required for electronic storage methods.) <i>Keep in mind that people should <u>never</u> be included in SV pictures. If a photo cannot be captured, please note the reason why in the “Additional Comments” section.</i>



Performance Standard 4

Performance Standard	Question	Evaluation Explanation
Performance standard #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? <i>Photo Required</i>	Ask provider for their catalog with portable diagnostic testing equipment information . This is a list of any portable equipment including serial/registration numbers. Answer “N/A” if they do not keep portable diagnostic equipment. Photograph the documentation provided. Inspectors are not required to evaluate the documentation for correctness. Simply photograph what is provided by the facility.
	2. Did the IDTF make the portable equipment or mobile unit(s) available for inspection?	Answer “N/A” if they do not keep portable diagnostic equipment or mobile unit(s).
	3. Does the IDTF maintain a current inventory of diagnostic equipment, including diagnostic testing equipment serial/registration numbers? <i>Photo Required</i>	Ask provider for an inventory of their current diagnostic equipment . This refers to physical equipment in the facility and their registration/serial numbers. If the provider states only portable equipment is used, answer “N/A,” and mention that only portable equipment was used in the comment box provided. Photograph the documentation provided. Inspectors are not required to evaluate the documentation for correctness. Simply photograph what is provided by the facility.
	4. Has the IDTF provided updates to the MACs regarding equipment changes in accordance with existing regulation?	Ask provider if they are updating their enrollment MAC regarding equipment changes . If the provider states they have not had any equipment changes, answer “No,” and record the provider’s response in the additional comments.

Performance Standards 5 and 6

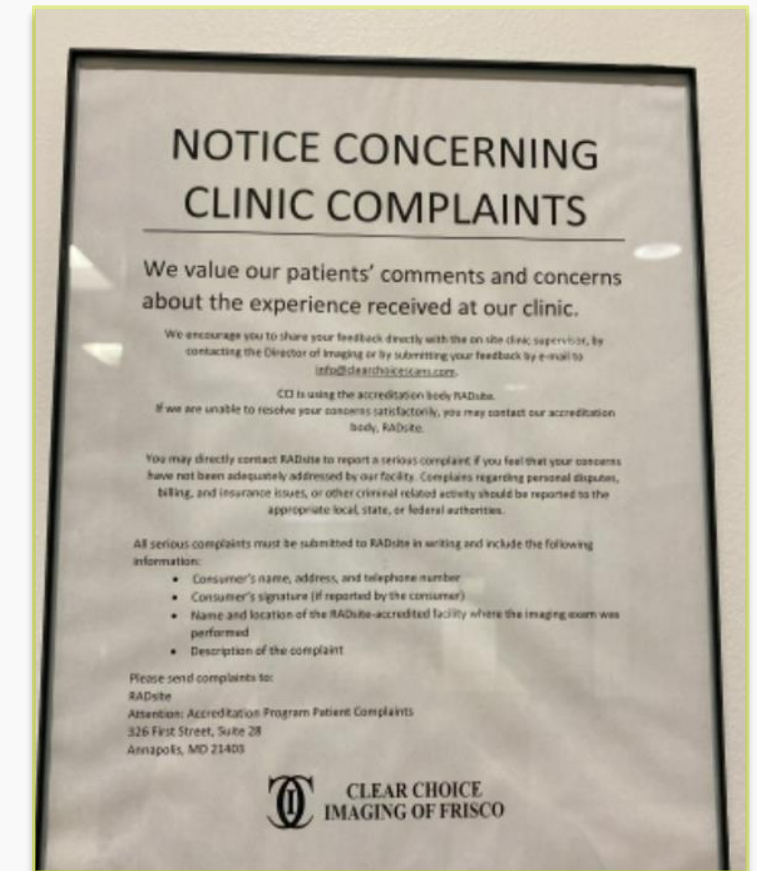
Performance Standard	Question	Evaluation Explanation
Performance standard #5 requires IDTFs to maintain a primary business phone under the name of the business.	1. Is the business telephone located at the IDTF or within the home office for the mobile IDTF?	Ask provider where their business telephone is located . If the provider states they do not have an adequate business phone, answer “ No ,” and record the provider’s response in the additional comments.
	2. Is the business telephone number listed in local telephone directory or is it available through directory assistance?	Ask provider for their business telephone number (if not posted). Using online search tools (e.g., YellowPages.com), search for the business’s information and compare to posted information or number given by provider.

Performance Standard	Question	Evaluation Explanation
Performance standard #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? <i>Photo required</i>	Ask provider for documentation showing they have comprehensive liability insurance (e.g., certificate of insurance showing amount of coverage). Photograph the documentation provided. Inspectors are not required to evaluate the documentation for correctness. Simply photograph what is provided by the facility.

Performance Standard 7 and 8

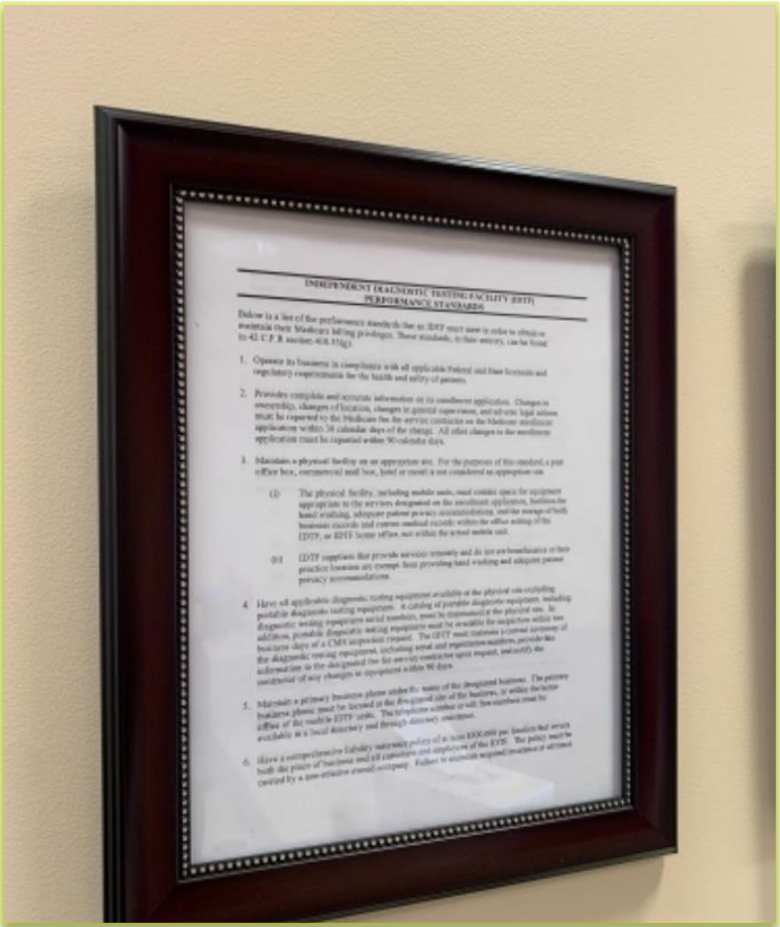
Performance Standard	Question	Evaluation Explanation
Performance standard #7 states that IDTFs must agree not to directly solicit patients; this includes, but is not limited to, a prohibition on telephone, computer, or in-person contacts.	How does the IDTF solicit new business?	Ask provider to describe how they solicit new business. Record provider's answer in the comment box for this question. When recording their response, begin the comment with "Provider stated..."

Performance Standard	Question	Evaluation Explanation
Performance standard #8 requires IDTFs to maintain a protocol regarding beneficiaries' complaints.	1. Does the supplier have a written complaint resolution procedure established? <i>Photo required</i>	Ask provider for a copy of their complaint resolution procedure (e.g., patient complaint resolution process). Photograph the <u>first two pages</u> of the documentation provided.



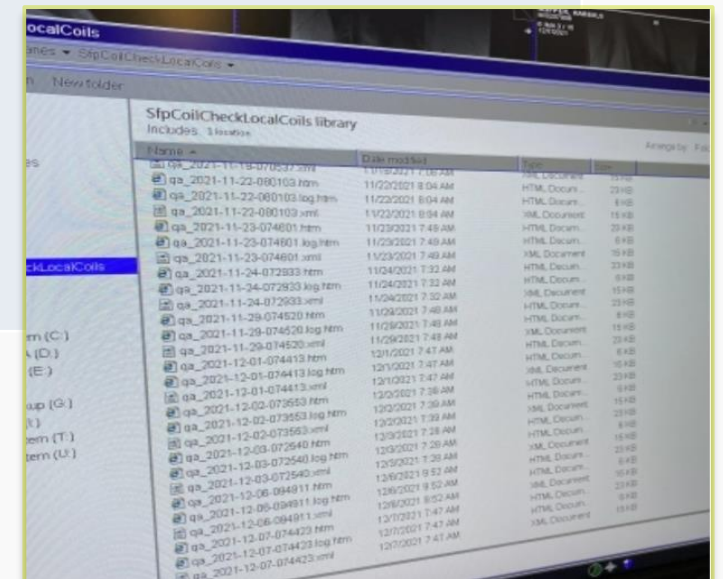
Performance Standard 9

Performance Standard	Question	Evaluation Explanation
Performance standard #9 requires IDTFs to post these standards for beneficiary review.	1. Has the IDTF posted the standards found at 42 CFR § 410.33 in the IDTF or home office for a mobile IDTF? <i>Photo required</i>	The IDTF Performance Standards (42 CFR § 410.33) should be posted in an area visible to the patients. Photograph the IDTF Performance Standards to demonstrate they are posted and visible to patients. <i>Keep in mind the presentation of the standards may vary (e.g., large poster, framed pages) but they must feature the reference number (42 CFR § 410.33).</i>



Performance Standard 11

Performance Standard	Question	Evaluation Explanation
Performance standard #11 requires IDTFs to have their diagnostic equipment calibrated and maintained per manufacturer's instructions and in compliance with applicable manufacturer's suggested maintenance and calibration standards.	1. Does the IDTF have proof that diagnostic equipment has been calibrated and maintained per equipment instructions in accordance with manufacturer's instructions? <i>Photo required</i>	Ask provider for proof the diagnostic testing equipment has been calibrated. If the provider cannot produce proof of calibration because EEG or mobile EEG does not need calibration, answer " No ," and record the provider's response in the additional comments. Photograph the <u>first two pages</u> of the documentation provided.
	2. Did the IDTF provide a copy of the maintenance log upon request? <i>Photo required</i>	Ask provider for a copy of the diagnostic testing equipment maintenance log(s). Photograph the <u>first two pages</u> of the documentation provided.



Performance Standard 12

Performance Standard	Question	Evaluation Explanation
Performance standard #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? <i>Photo required</i>	Ask provider for proof individuals performing services have the applicable Federal/State licenses and/or certifications. Photograph the documentation provided. <i>Ensure there is <u>no PII</u> (e.g. date of birth, Social Security number) on the document before taking a picture. If PII is present, ask the provider to give a different document or to hide the PII before photographing.</i>
	2. Can technical staff identify the supervising physician(s)?	Ask technical staff (technician) to provide the name(s) of the supervising physician(s). Answer “ Yes ” and list the name(s) provided, if they can provide the name(s). Answer “ No ,” if they cannot provide the name(s).
	3. Is the supervising physicians(s) on site?	If answered “ No ,” ask the provider why the supervising physician is not on site and record reason.



Performance Standard 12

Performance Standard	Question	Evaluation Explanation
Performance standard #12 requires IDTFs to have technical staff on duty with the appropriate credentials to perform the tests.	4. Did the IDTF provide a written list of the technician(s) that will be furnishing services at this IDTF upon request? <i>Photo required</i>	Ask provider for a list of the technician(s) that will be furnishing services at this IDTF. Photograph the documentation provided. <i>Ensure there is <u>no PII</u> (e.g., date of birth, Social Security number) on the document before taking a picture. If PII is present, ask the provider to give a different document or to hide the PII before photographing.</i>
	5. Did the IDTF provide a written list of the supervising physician(s) that will be supervising services at this IDTF upon request? <i>Photo required</i>	Ask provider for a list of the supervising physician(s) that will be supervising services at this IDTF. Photograph the documentation provided. <i>Ensure there is <u>no PII</u> (e.g., date of birth, Social Security number) on the document before taking a picture. If PII is present, ask the provider to give a different document or to hide the PII before photographing.</i>

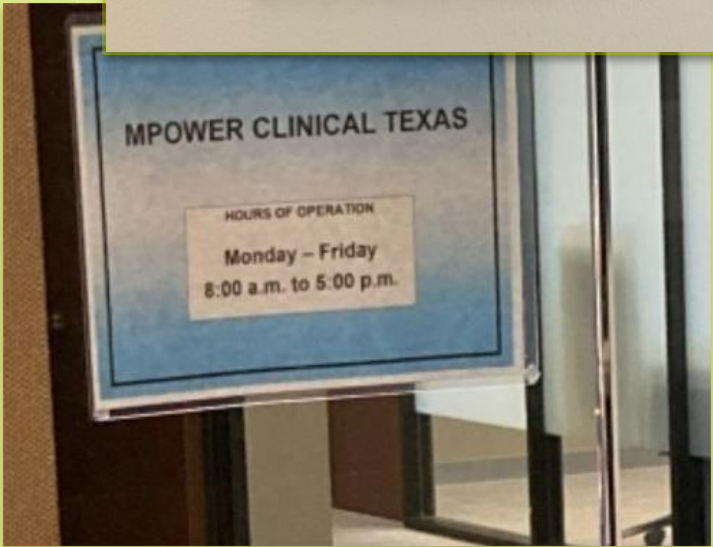
Performance Standard 13

Performance Standard	Question	Evaluation Explanation
Performance standard #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?	Ask provider how much time is needed to retrieve medical records .
	2. Does the IDTF have proper medical records storage?	Ask to see how medical records are stored . Answer “ Yes ,” if they have a secure storage system that limits access to appropriate parties (e.g., locked filing cabinet, locked storage room/facility, login-required electronic system). Answer “ No ,” if they do not have a secure storage system (e.g., filing cabinet or storage room/facility without lock).
	3. How are the records stored? <i>Photo Required</i>	Select the appropriate answer regarding how medical records are stored: • On-site – <u>Physical</u> patient files are maintained at the facility visited • Storage Facility – <u>Physical</u> patient files are maintained in storage facility that is off-site • Electronically – <u>Digital</u> patient files are stored in database and accessible electronically Photograph the storage of the medical records. For electronic storage methods, photograph the computer and enter an explanation in the comments. <i>Do not review active patient files. Inspectors <u>must never</u> look at or photograph information in actual patient files.</i>



Performance Standard 14

Performance Standard	Question	Evaluation Explanation
Performance standard #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?	Answer "Yes," if the facility was open during their posted hours of operation. If there are no hours posted, assume their operating hours are from 9 AM to 5 PM. Answer "No," if the facility was closed during the location's hours of operation.
	2. Does the facility maintain posted hours of operation? <i>Photo required</i>	Answer "Yes" and record the hours of operation, if the hours of operation are visibly posted at the site. Answer "No," if the hours of operation are not posted. Photograph the hours of operation physically posted at the facility.



Performance Standard #15

Performance Standard	Question	Evaluation Explanation
Performance standard #15 states that with the exception of hospital-based and mobile IDTFs, a fixed-base IDTF is prohibited from sharing its practice location, diagnostic equipment, or leasing/subleasing its operations or practice.	1. Does the IDTF share its practice location? <i>Photo Required</i>	Ask provider if they are sharing their practice location with another individual or organization? Observe the facility for indication that another business is occupying the same space (e.g. multiple mobile providers sharing same home office, multiple business names on office door). Photograph evidence that the space is shared.
	2. Does the IDTF share diagnostic equipment?	Ask provider if they are sharing their diagnostic equipment with another individual or organization?
	3. Does the IDTF lease or sublease its operation or its practice?	Ask the provider if they are leasing/subleasing their operations or practice to another individual or organization?

Additional Comments

Performance Standard	Question	Evaluation Explanation
Additional Question for Inspector	Additional Comments	Use the Additional Comments section to provide additional information that may help the MAC process the provider's enrollment application. Examples include but are not limited to: • What actions were taken to determine a site was closed • Explanation of why a second site visit is needed (e.g.; provider was closed, staff could not be located) • Why a required picture could not be obtained • Recording name and position of individual that was not referenced in "Name of Authorized Representative(s) or Interviewee(s)"

Additional Comments *

Equipment calibration is conducted by the manufacture and no additional calibrations are needed. All patients are seen in their homes not in the office location.

Additional Comments *

The complaint forms are online for customers. It is in the form of an email only. There is no log for the complaints because there have not been any complaints in the past.
No photos were taken of the hand washing station or patient privacy area because no patients are seen in this facility.

Required Photos

Required Photos:

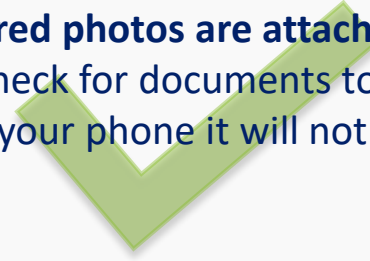
- Exterior of building
 - If there is no facility on site, photographs of street signs and/or landmarks surrounding location
- IDTF's entrance (including business signage and hours of operation if posted)
- How the facility is accessible to the disabled (how they enter the facility)
- Interior of facility showing:
 - Space for equipment appropriate to the services offered
 - Facilities for hand washing
 - Adequate patient privacy accommodations
 - The storage of business records
 - The storage of current medical records within the office setting of the IDTF, or IDTF home office, not within the actual mobile unit
- ALL diagnostic testing equipment (including a photo of the equipment and the serial/registration number(s) on each piece of equipment)
- Catalog of portable diagnostic testing equipment (if applicable)
- Proof of liability insurance
- Written complaint resolution procedures and forms
- Posted 42 CFR § 410.33 standards
- Diagnostic testing equipment calibration log
- Diagnostic testing equipment maintenance log
- All applicable federal and state licenses
- List of all technicians furnishing services at the IDTF
- List of supervising physicians supervising services at the IDTF
- Evidence that the IDTF is sharing their practice location (if applicable)

Completing the Site Visit

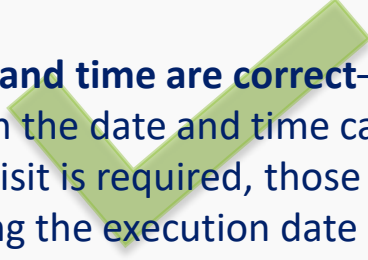
At minimum, the report should contain all the required elements before submitting for review.



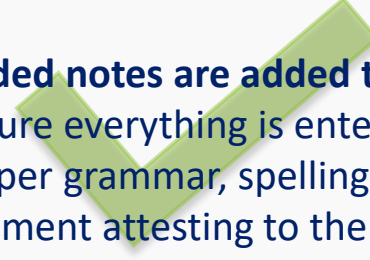
First and foremost, check that business name is correct– The business name must match what is listed in the Job Order Details. If the facility operates under a different name, the relationship must be verified and a note entered in Additional Comments.



Check that all required photos are attached, clear, and have geotagging data– Check for documents to be easy to read (if you can't read it on your phone it will not be readable in the report).



Check that the date and time are correct– The inspection date and time must match the date and time captured with the photos. If a second visit is required, those dates and times must match, including the execution date at the signature.



Check that any needed notes are added to Additional Comments– Make sure everything is entered in complete sentences using proper grammar, spelling, and formatting. Be sure to enter a statement attesting to the accuracy of photos.



Check that only ONE facility type is marked “Yes”– All other facility types should be marked “No.”



Check the signature and name are entered– The Printed Name and signature fields indicate that the report is true and complete.

Click “Submit for Review” to complete the site visit.