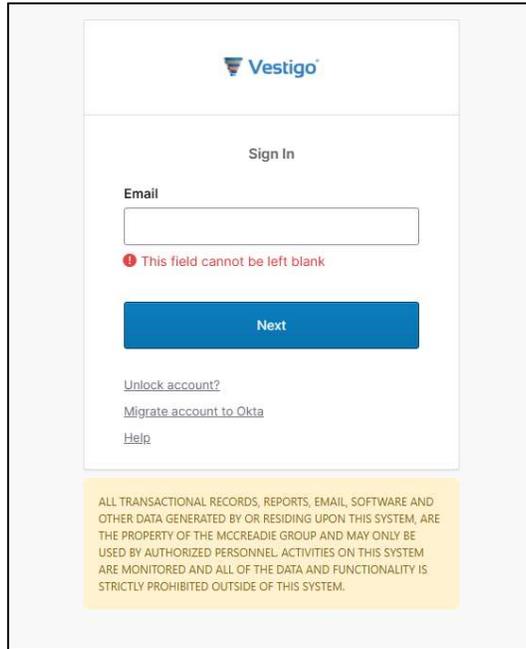


A Monitor's Guide to Vestigo Verify

1. Log into Vestigo Verify at <https://monitor.vestigo.biz/> using the credentials you setup your account for.

NOTE: Your Vestigo account is NOT site specific and can be used when monitoring any site that utilizes this IP accountability system.



2. Once logged in, this is the space where you will be able to find the protocols that you have been granted access to during your study visit. Click on **“View Protocol”** to go into the study.

[Review the Help Document](#)

[My Visits](#) | [My Protocols](#) | [My Calendar](#) | [My Visit Notes](#) | [My Communication History](#)

Home

Visit Date: Through

If you do not see the visit, please confirm that you are using the correct email address or contact the site to confirm the email address that was used.

Site	Visit #	Status	Scheduled Visit	Access Granted	Visit Purpose	Visit Type	
Duke Medical Center - IDS Duke Clinic 200 Trent Dr, Duke Clinic Room 0101b Yellow Zone Durham, NC 27710	#458836	In Progress	14 May 2025 15:00:00- 14 May 2026 16:00:00 EDT	14 May 2025 15:00:00- 14 May 2026 16:00:00 EDT	Interim	Fully Remote	View Protocols
Duke Medical Center - IDS Duke Clinic 200 Trent Dr, Duke Clinic Room 0101b Yellow Zone Durham, NC 27710	#456451	In Progress	06 May 2025 15:00:00- 14 May 2026 18:15:53 EDT	06 May 2025 15:00:00- 14 May 2026 18:15:53 EDT	Interim	Fully Remote	View Protocols

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3. After clicking on “**View Protocol**,” click on the “View Protocol again as shown below.

My Visits | My Protocols | My Calendar | My Visit Notes | My Communication History

Home Visit

Visit #411112: IDS Duke Clinic
Access Dates/Times: 15 Nov 2024 15:00:00 - 15 Nov 2025 19:33:00 EST (Ends in 6 months)
For Assistance for this visit, contact IDS.pharmacy@duke.edu

Notes:
 Logistic Notes:

Protocol	Title	Lead Sponsor	
TEST - P1627	IDS TEST Protocol	IDS TEST Protocol	View Protocol

4. Once you’re logged into the protocol, below will be the main monitor’s page where you can navigate around to find the documentation needed to conduct your visit.

My Visits | My Protocols | My Calendar | My Visit Notes | My Communication History

Home Visit Protocol

Protocol Numbers: TEST | P1627 **PI:** No PI Recorded.
Title: IDS TEST Protocol

Visit Summary Report: Visit #411112 - Visit Start: 15 Nov 2024 - Monitor: [REDACTED] [View](#)

Protocol | **Inventory** | Returns | Documents | Accountability | Visit Notes | Monitor Review | AuditLog | Temperature Documents | Reports

Protocol Status: Enrolling by invitation
Lead Sponsor: IDS TEST Protocol
Phase: N/A
Intervention Type: Drug
Blinded Study:
Study Design: IDS TEST Protocol

5. The **Inventory Tab** provides the current quantity on hand for IP that has been built for the study. Clicking on the drug name will allow you to verify drug ID numbers if provided. You are also able to see DARF notes specific to the drug on this page by clicking “**Show DARF Notes.**”

Protocol | **Inventory** | Returns | Documents | Accountability | Visit Notes | Monitor Review | AuditLog | Temperature Documents | Reports

▼ **Drugs**

Drug	Dose Amt/Units	Inventory Units	QOH		
ADASDAD FROZEN	100 MG/ML	VIAL	21	Add Visit Note	Show DARF Notes (1)
Monitor view TEST	100 ML	KIT	97	Add Visit Note	Show DARF Notes (1)
Monitor view TEST	100 BAG	BAG	0	Add Visit Note	
SPC/DCT Kits	1 KIT	KIT	7	Add Visit Note	
Study Drug or PBO Kits	1 BLISTERPAK	KIT	40	Add Visit Note	

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6. The **Returns Tab** allows the monitor to select a drug and authorize or cosign for IP that the site has quarantined, destroyed, or is awaiting approval for return to sponsor.

The screenshot shows the Vestigo Verify interface with the 'Returns' tab selected. The top navigation bar includes 'My Visits', 'My Protocols', 'My Calendar', 'My Visit Notes', and 'My Communication History'. Below this, there are links for 'Home', 'Visit', and 'Protocol'. The main content area displays protocol information: 'Protocol Numbers: TEST | P1627' and 'Title: IDS TEST Protocol'. A 'Visit Summary Report' section shows 'Visit #458836 - Visit Start: 14 May 2025 - Monitor: Monitor Email, Wyatt Test' with a 'View' button. A navigation menu includes 'Protocol', 'Inventory', 'Returns', 'Documents', 'Accountability', 'Visit Notes', 'Monitor Review', 'AuditLog', 'Temperature Documents', and 'Reports'. The 'Drug' dropdown is set to '0.9% Sodium Chloride for Injection, USP'. Below the drug name are buttons for 'Returns', 'Quarantine', 'Destroyed', and 'Returned to Sponsor'. A 'Transactions' table header is visible with columns: 'Quarantined Date', 'Lot', 'Item', 'Qty', 'Unit', 'Inventory Expiration Date', 'Source', 'Return Comments', 'Quarantined', 'Verification Required', 'Verified By', and 'Authorized'. Below the table, a message states 'Sorry your search returned no results'. At the bottom, there are two buttons: 'Authorize Destruction' and 'Authorize Return To Sponsor'.

7. The **Documents Dropdown Menu** provides the monitor access to a variety of protocol specific and site-specific records.

This screenshot is identical to the previous one, but with the 'Documents' dropdown menu open. The menu options are: 'Protocol Documents', 'Transaction Documents', 'Facility Documents', and 'Competency Documents'. The rest of the interface, including the navigation bar, protocol information, visit summary, and transaction table, remains the same.

8. **Protocol Documents** provide the monitor with protocol specific documents (e.g., communication memos, IDS DOA, and historical shipping receipts, protocol NTFs).

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9. Transaction Documents provide the monitor with files and documents that are attached to participant dispensing, shipping receipts, historical shipping receipts.

My Visits | My Protocols | My Calendar | My Visit Notes | My Communication History

Home | Visit | Protocol

Protocol Numbers: TEST | P1627
Title: IDS TEST Protocol

PI: No PI Recorded.

Visit Summary Report: Visit #458836 - Visit Start: 14 May 2025 - Monitor: Monitor Email, Wyatt Test [View](#)

Protocol | Inventory | Returns | Documents | Accountability | Visit Notes | Monitor Review | AuditLog | Temperature Documents | Reports

Transaction Documents

Prescriptions

File Name	Service Date	Rx Number	PSN	Certified	File Create User/Date
Sorry your search returned no results					

Shipping Receipts

File Name	Service Date	Invoice Number	Facility	Certified	File Create User/Date
IDS - Drug Destruction Policy 12.2022.pdf	27 Feb 2023 13:05:14 EDT	test	IDS Duke Clinic		th65 (27 Feb 2023 13:07:05 EST) View

Patient Documents

File Name	PSN	Facility	Certified	File Create User/Date
Sorry your search returned no results				

Drug Returns

File Name	Drug	Return Date	Lot	Item Number	Source	Certified	File Create User/Date
Sorry your search returned no results							

Historical Shipping Receipts

File Name	Service Date	Invoice #	Facility	Certified	File Create User/Date
Sorry your search returned no results					

Patient Visit Transaction Documents

File Name	PSN	Schedule	Visit Date	Fill Date	Certification	Filled by RX	File Create User/Date	Last Modified User/Date
Sorry your search returned no results								

10. Facility Documents provide the monitor with files and documents that are associated with the site and not any one protocol (e.g., policies, staff licensures, NTFs).

Protocol | Inventory | Returns | Documents | Accountability | Visit Notes | Monitor Review | AuditLog | Temperature Documents | Reports

Policies & Procedures

File Name	Facility	Certified	File Create User/Date
IDS - Temperature Monitoring Policy 12.2022.pdf	IDS Duke Clinic		th65 (17 Feb 2023 16:35:38 EST) View
IDS - Purchase of Investigational Agents Policy 12.2022.pdf	IDS Duke Clinic		th65 (01 Feb 2023 16:35:32 EST) View
IDS - Investigational Drug Services Overview Policy 12.2022.pdf	IDS Duke Clinic		th65 (01 Feb 2023 16:35:24 EST) View
IDS - Drug Destruction Policy 12.2022.pdf	IDS Duke Clinic		th65 (01 Feb 2023 16:35:16 EST) View

Facility Licensure & Certificates

File Name	Facility	Certified	File Create User/Date
Sorry your search returned no results			

Staff Licensure & Certificates

File Name	Facility	Certified	File Create User/Date
[REDACTED]	IDS Duke Clinic		th65 (17 Apr 2025 14:46:07 EDT) View
[REDACTED]	IDS Duke Clinic		th65 (15 Jan 2025 12:14:04 EST) View
[REDACTED]	IDS Duke Clinic		th65 (15 Jan 2025 12:14:04 EST) View
[REDACTED]	IDS Duke Clinic		th65 (15 Jan 2025 12:14:04 EST) View
[REDACTED]	IDS Duke Clinic		th65 (15 Jan 2025 12:14:04 EST) View
[REDACTED]	IDS Duke Clinic		th65 (19 Dec 2024 09:46:52 EST) View
[REDACTED]	IDS Duke Clinic		th65 (20 Nov 2024 14:30:33 EST) View
[REDACTED]	IDS Duke Clinic		th65 (25 Sep 2024 12:34:04 EDT) View
[REDACTED]	IDS Duke Clinic		th65 (17 Jul 2024 14:06:21 EDT) View
[REDACTED]	IDS Duke Clinic		th65 (08 Feb 2024 13:32:56 EST) View

10 Rows | 1 | 2

Notes to File

File Name	Facility	Certified	File Create User/Date
[REDACTED]	IDS Duke Clinic		th65 (02 Jan 2025 10:05:31 EST) View

Other

File Name	Facility	Certified	File Create User/Date
Sorry your search returned no results			

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11. **Competency Documents** provide the monitor with the competency/training records that have been uploaded for that specific protocol.

12. The **Accountability Tab** is where the monitor can generate an accountability record for each drug that is built in the protocol.

i. The date range is customizable.

ii. The Form dropdown menu can be changed based on the type of type of DAR needed.

iii. You can run a subject specific accountability by clicking the subject dropdown menu.

iv. Some drugs might have multiple locations. To select a single location, click on the location within the dropdown menu.

v. If you would like to include subject initials, blind subject numbers, etc., you must check the box before you generate the accountability record.

The screenshot displays the 'Accountability' tab in the Vestigo Verify application. At the top, there are navigation tabs: 'My Visits', 'My Protocols', 'My Calendar', 'My Visit Notes', and 'My Communication History'. Below this, the 'Home Visit Protocol' section shows 'Protocol Numbers: TEST | P1627' and 'Title: IDS TEST Protocol'. A 'PI: No PI Recorded.' message is also visible. The 'Visit Summary Report' section includes a dropdown menu for 'Visit #456451 - Visit Start: 06 May 2025 - Monitor: Monitor Email, Wyatt Test' and a 'View' button. A secondary navigation bar contains tabs for 'Protocol', 'Inventory', 'Returns', 'Documents', 'Accountability', 'Visit Notes', 'Monitor Review', 'AuditLog', 'Temperature Documents', and 'Reports'. The main form area is titled 'Drug' and contains several fields: 'Drug' (0.9% Sodium Chloride for Injection, USP), 'Form' (IDS), 'Date' (24 Aug 2018) and 'To' (14 May 2025), 'Subject' (None selected), 'Inventory' (None selected), 'Location' (IDS-Duke Clinic Room Temp - Room 0101b), and checkboxes for 'Include Temperature Excursions', 'Include Subject and Inventory Returns', 'Include Cycle Counts', and 'Show Subject Initials?'. A 'Generate Accountability Record' button is located at the bottom left of the form.

13. The **Visit Notes Tab** is where the monitor will enter any notes for the site to see after/during the monitoring visit. Once you click Add Visit Note, you can select to add a **Comment** or an **Action Item**. An action item alert will be sent to the site for a response. After responding, the status will change to **"Pending Monitor Review."** A site response is required to mark the item as **"complete."**

14. The **Monitor Review Tab** is where the monitor can set parameters to view transactions. When clicking the checkbox and selecting **"Mark as Reviewed,"** this indicates the monitor agrees with the transaction.

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15. The **Audit Log Tab** provides the monitor with any changes on the protocol related to 21 CFR Part 11 regulation. There are four sections in the audit log that can be reviewed.

- i. Inventory
- ii. Patients
- iii. Prescriptions/Fills
- iv. Protocols/Arms/Drugs

16. The **Temperature Documents Tab** is where the monitor can view temperature logs by location. Once you click **"View Files,"** you can find the calibration certificate for that equipment, temperature logs, and any excursion documentation associated with that storage location.

My Visits | My Protocols | My Calendar | My Visit Notes | My Communication History

Home | Visit | Protocol

Protocol Numbers: TEST | P1627
Title: IDS TEST Protocol

PI: No PI Recorded.

Visit Summary Report: Visit #456451 - Visit Start: 06 May 2025 - Monitor: Monitor Email, Wyatt Test [View](#)

Protocol | Inventory | Returns | Documents | Accountability | Visit Notes | Monitor Review | AuditLog | **Temperature Documents** | Reports

Date: 15 May 2024 To: 15 May 2026 Location: All selected (6) [Search](#)

Temperature Documents

	Temp Log Start Date	Temp Log End Date	Location	Last Modified
View Files	01 Jan 2025 00:00:00 EDT	31 Dec 2025 23:59:00 EDT	DCT Pharmacy Ambient	mz113 (03 Feb 2025 09:23:33 EST)

Temperature Documents

Temperature Logs

File Name	Temp. Log Start Date	Temp. Log End Date	Location	Facility	Certified	File Create User/Date	
179479 - DCT Pharmacy Ambient 2025 Templogs.pdf	01 Jan 2025 00:00:00 EDT	31 Dec 2025 23:59:00 EDT	DCT Pharmacy Ambient	IDS Duke Clinic		mz113 (01 May 2025 16:44:00 EDT)	View

Calibration Certifications

File Name	Temp. Log Start Date	Temp. Log End Date	Location	Facility	Certified	File Create User/Date
Sorry your search returned no results						

Communications

File Name	Temp. Log Start Date	Temp. Log End Date	Location	Facility	Certified	File Create User/Date
Sorry your search returned no results						

Temperature Excursions

File Name	Temp. Log Start Date	Temp. Log End Date	Location	Facility	Certified	File Create User/Date
Sorry your search returned no results						

17. The **Reports Tab** is where the monitor can view and download different types of reports that might be needed to conduct their visit. Under this tab, you can also view and download pharmacy training reports specific to a certain training on the protocol.

Protocol | Inventory | Returns | Documents | Accountability | Visit Notes | Monitor Review | AuditLog | Temperature Documents | **Reports**

Reports

Report	
Authorized Prescribers for this Protocol	View
Protocol Dispensing History with Returns	View
Active Inventory Report	View
Inventory in Quarantine Report	View
Prescription Returns Report	View
Pharmacy Training Records	View