

FDA Pilot to Measure VRS Readiness

Report for the FDA

May 21, 2020

Prepared by



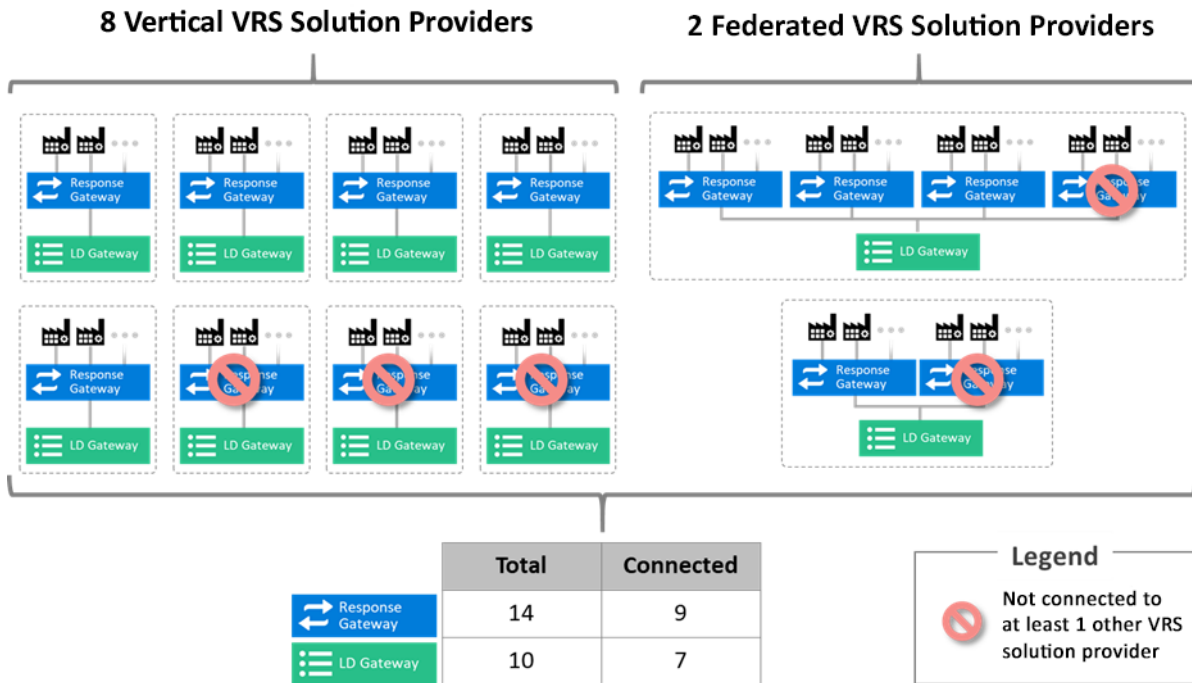
Contents

1	Executive Summary	4
1.1	Purpose of the Pilot	4
1.2	Background and Scope.....	4
1.3	Structure of this Report	5
2	FDA Pilot Overview	6
2.1	Evolution of Testing	6
2.1.1	History of Progress	6
2.1.2	Current Status.....	6
2.2	Benefits of Merging with HDA-Sponsored VRS Testing	7
2.3	Pilot Scenarios and Approach	8
2.3.1	VRS Solution Providers	9
2.3.2	Vendor Solutions	10
2.3.3	Connections.....	10
	11
2.3.4	In-house Solutions	11
2.4	Results Verification	12
2.4.1	Documenting and Automating Verification.....	12
2.4.2	Vantage Responsibilities.....	13
2.5	Test Cases.....	14
2.5.1	VRS Request/Response Testing	14
2.5.2	LD Router Testing	15
3	Pilot Results & Observations.....	16
3.1	LD Synchronization Test Results	17
3.1.1	Connection Details.....	17
3.1.2	LD Synchronization Results.....	18
3.2	Request/Response Test Results	19
3.2.1	Summary Request/Response Results.....	19
3.2.2	Detailed Request/Response Results.....	21
4	Final Observations	23
5	Appendix.....	24
5.1	Acronyms and Terminology	24
5.2	FDA Enforcement Delay on Saleable Returns Verification	25
5.3	Original FDA Pilot Test Cases	26

5.4 VRS Request/Response Test Case Detailed Descriptions 28

5.5 About the Authors 32

Each VRS solution provider attempted to simulate VRS requests to a total of 14 Response Gateways. Each Response Gateway provider was connected to the VRS network via one of 10 possible Lookup Directory (LD) Gateways. By the end of the pilot, nine Response Gateways were able to connect to other VRS solution providers and generate test results for evaluation in this final report.



1.3 Structure of this Report

Section 2: Provides details of the testing process and participants.

Section 3: Provides the aggregated results of the testing.

Section 4: Provides final observations and lessons learned.

2 FDA Pilot Overview

2.1 Evolution of Testing

2.1.1 History of Progress

The HDA sponsored the development of the VRS, which started in 2018 and culminated in Round 1 of integration tests among VRS solution providers from the fourth quarter of 2018 to the second quarter of 2019. In April 2019, the HDA published its final report, entitled “[VRS Task Force Report to Industry](#).”

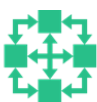


Round 1

The first round of integration testing among VRS solution providers occurred from the fourth quarter of 2018 to the second quarter of 2019. It offered limited visibility into the readiness of the VRS network to meet the U.S. Drug Supply Chain Security Act (DSCSA) 2019 deadline for saleable returns. Test execution was based on each VRS solution provider’s understanding of the VRS requirements; actual testing and reporting was provided by the VRS solution providers against their own solutions.



This pilot was designed to provide independent and quantifiable metrics about the readiness of the VRS network. Instead of each VRS solution provider performing self-tests and self-reporting its readiness, rfxcel executed a set of test cases against each provider. The test cases were based on the VRS requirements and GS1 specifications. Vantage reviewed the final results to ensure completeness and to avoid bias. Testing started in the third quarter of 2019 but stalled due to connection issues which were impacted further in the fourth quarter as many VRS solution providers had moved to new quality assurance environments in preparation for the November 2019 deadline — a move that broke working connections.



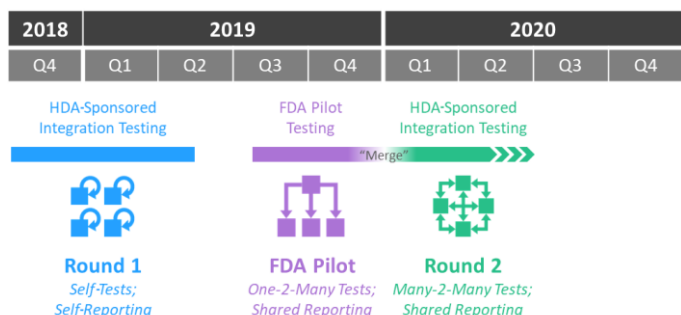
Round 2

Restoring connections was difficult. Coordinating resources across VRS solution providers was challenging due to their individual priorities and holiday schedules in the fourth quarter of 2019. Because VRS solution providers were unavailable during the holidays in the fourth quarter of 2019 and were focused on meeting the November 2019 deadlines, the pilot end date was extended to the first quarter of 2020. This coincided with a second round of HDA-sponsored testing. To maximize the HDA’s efforts, the pilot was “merged” with HDA-sponsored testing by adopting the new HDA test cases and offering our approach and learnings from the initial pilot testing to the VRS solution providers participating in the HDA-sponsored testing.

2.1.2 Current Status

Round 2 testing is expected to continue beyond the second quarter of 2020 but the first cycle of testing is currently paused to allow VRS solution providers time to update their solutions to meet the new GS1 Messaging Standards which were released on March 2020.

The results from the first cycle of testing occurred from March 20 through April 17 of 2020 and are used as the basis of reporting for this pilot.



2.2 Benefits of Merging with HDA-Sponsored VRS Testing

At the start of this FDA pilot, the HDA had not announced that it would sponsor a second round of testing. Once it made the announcement, however, rfxcel and Vantage decided to “merge” its pilot efforts with the HDA testing efforts, as both had the same goals.

As part of the “merge” effort, our pilot team presented its best practices to the HDA group and worked with the different sub-groups to reach consensus and facilitate adoption of these processes. The pilot group helped to influence the following changes in testing approaches between Round 1 and Round 2:

- **Independent testing.** Instead of each VRS solution provider testing their own systems and reporting on the results, Round 2 testing is being performed by multiple VRS solution providers testing against each other. The HDA group opted for a “Many-to-Many” test approach, which requires each solution provider to test every other provider and, therefore, offers a much more extensive test coverage. This is an expansion of the pilot’s original “One-to-Many” testing approach in which rfxcel (the “one”) tested against other VRS solution providers (the “many”).
- **Standardized test cases.** Instead of each VRS solution provider testing based on its own test cases, Round 2 testing is based on a set of test cases approved by a cross-section of VRS solution providers. A sub-work group developed the common test cases. The larger working group approved these test cases before testing started to ensure that all relevant test case scenarios are being covered.
- **Aggregated results.** To provide a status to the industry, Round 2 testing is using an aggregated progress report that does not focus on specific providers. Because this round involves aggregating a significant amount of test data, Vantage was also approved by the HDA working groups to serve as the independent reviewer and aggregator of information.

***NOTE:** Results will be shown for both the “One-to-Many” and “Many-to-Many” testing approaches to acknowledge both the FDA pilot and the transition to the HDA-sponsored work group testing.*

2.3 Pilot Scenarios and Approach

This pilot is intended to test and quantify the readiness of the VRS network in accordance with the test scenarios outlined below. The initial test cases were developed using the HDA test cases as a starting point, and were augmented with the latest VRS specifications to provide more detailed coverage. As part of the “merge” effort with the HDA Round 2 testing, the pilot has adopted the test cases used by the HDA Round 2 workgroup. Table 1 summarizes the similarities and notes differences between the original and revised test approach.

Table 1. Pilot Testing Comparison

Original Test Approach	Revised Test Approach (HDA Round 2)
<p>One-to-Many verification: rfxcel executed the test cases and reported aggregated results against the VRS solution providers. Vantage reviewed the results for accuracy.</p>	<p>Many-to-Many verification: The HDA testing approach requires all providers to test based on a common set of test cases. Vantage aggregates the group results.</p>
<p>Original VRS test cases: The original VRS test cases are in the appendix of this report. To complete the pilot and contribute to the larger HDA-sponsored test effort, the remainder of the pilot will use the latest HDA test cases.</p>	<p>Revised VRS test cases: The revised approach is based on the test cases developed by the HDA VRS working group. It consolidates test cases from VRS solution providers. The Revised VRS Test Cases differ in the following ways:</p> <ul style="list-style-type: none"> • Case-sensitive lot: Verification of lot IDs is expected to match by upper/lowercase. • Day 00 Expiration: Verification of a 00 expiry date has been included. • Deleted Global Trade Identification Numbers (GTINs): Verification of logically deleted GTINs in the LD must fail.

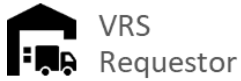
Although a different test script has been adopted for this pilot the test approach for the pilot testing is still organized around two key scenarios:

Key Pilot Test Scenarios

- 1 LD Synchronization:** These test cases were designed to verify the ability of VRS solution providers to trade LD updates among all providers. The synchronization testing focused on the ability to *push* and *pull* LD information from different LD providers. A by-product of LD testing is to ensure that VRS solution providers are connected and that master data has been exchanged to support the Request/Response testing described below.
- 2 Request/Response:** By merging the pilot with the HDA Round 2 testing, the Request/Response testing will be based on a Many-to-Many testing approach. As part of this approach, rfxcel will execute One-to-Many Request/Response test cases against connected VRS solution providers to measure their readiness. The One-to-Many results will also be presented to provide additional insight into the readiness of the VRS network.

2.3.1 VRS Solution Providers

We will use the following terms to describe the participants in the VRS network.



VRS Requestor

A VRS Requestor provides a Verification/VRS Request (i.e., “ask”) if a product is approved for resale in accordance with the VRS requirements. Most often, these are wholesalers and distributors. For this pilot, however, the role of the VRS Requestor will be simulated by participating VRS solution providers (e.g., rfxcel).



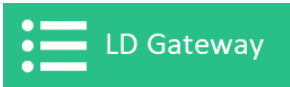
VRS Responder

A VRS Responder provides a Verification/VRS Response (i.e., “answer”) to a VRS Requestor to confirm if a product is approved for resale per the VRS requirements. These are manufacturers and repackagers responsible for serialization of a product. Most often, the VRS Response has been outsourced to a Response Gateway, such as the participating VRS vendors.



Response Gateway

A Response Gateway provides the proper GS1-formatted Response to a VRS Request and manages all associated system requirements, such as logging, error handling, and load balancing. All Response Gateways in this pilot are provided by vendors.



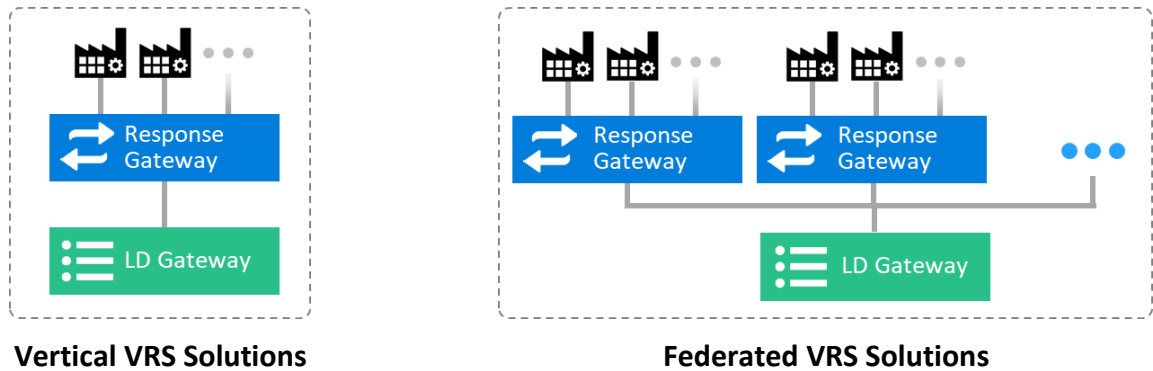
LD Gateway

Verification Requests are initiated via a LD Gateway, which is responsible for three key functions in the VRS network: 1) routing requests to the appropriate Response Gateway; 2) ensuring that the LD is properly updated based on update notifications from other LD Gateways; and 3) publishing updates to other LD Gateways based on changes to the Response Gateways with which they are associated. All LD Gateways in this FDA pilot are provided by vendors.

2.3.2 Vendor Solutions

During testing, only vendor-developed VRS solutions were available for evaluation. All tested vendor solutions were structured according to one of the of solution architectures shown in Figure 1.

Figure 1. VRS Solution Architectures



Vertical VRS solution providers offer both Response Gateway and LD Gateway functionality via a **common vendor**. This solution is most often provided by a vendor that also offers serialization and compliance solutions.

Federated VRS solution providers use a structure that allows multiple Responders to connect through one LD Gateway. The **LD Gateway** is managed by **one provider** while **Response Gateways** are provided by **different vendors**.

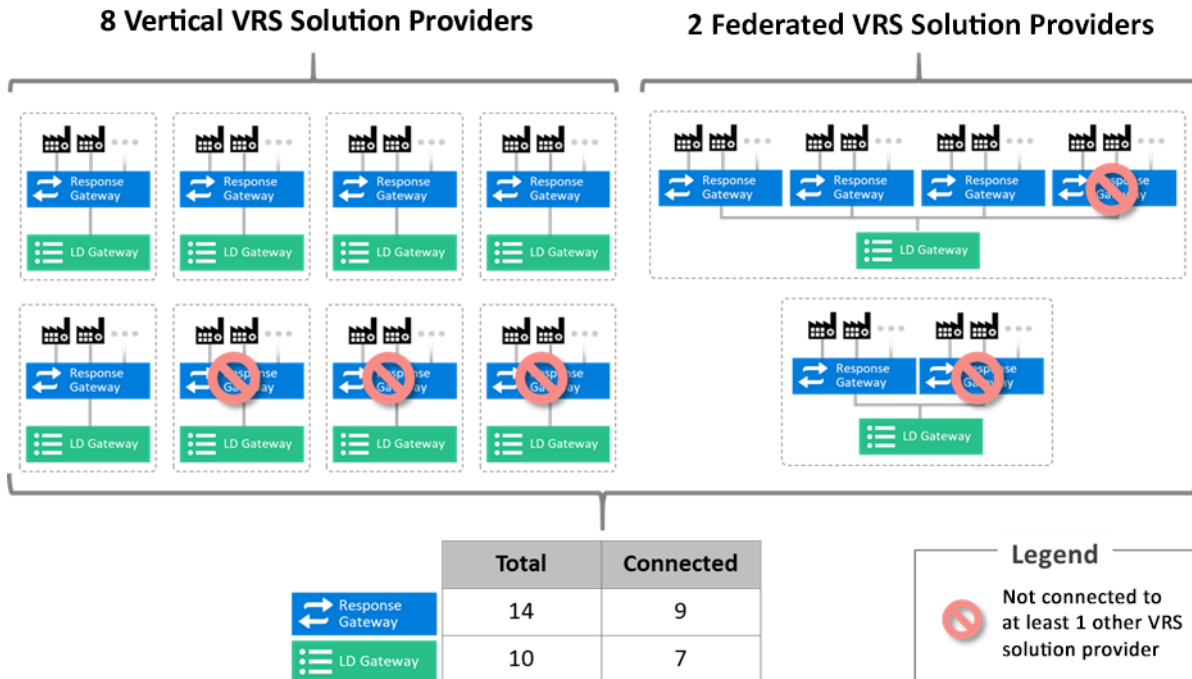
2.3.3 Connections

To ensure that relevant information was evaluated, the pilot results were limited only to VRS solution providers that could connect with other VRS solution providers. To be considered “connected,” the solution provider must meet three criteria:

1. Share and configure Web security certificates to enable LD and Request/Response services to exchange data
2. Ensure that a valid LD update can be pushed or pulled to the other VRS solution
3. Ensure that a Request/Response cycle can be passed using a positive product identifier (PI).

If a provider could connect to at least one other provider under these conditions, it was considered connected and its test results were aggregated for this report. These connected gateways were split between five connected vertical and two connected federated VRS solution providers, as shown in Figure 2 on the next page.

Figure 2. VRS Network



- **Connected solutions.** Nine Response Gateways and seven LD Gateways were considered *connected* tested are included in the pilot test results.
- **Unconnected solutions.** Five Response Gateways were not connected to any other provider during the pilot time frame and are not included in the pilot test results.
- **Average number of connections.** Although only connected VRS solution providers were evaluated, there were still gaps in connectivity among many participants. Only one VRS solution provider had established connections to every other participating provider. On average, each VRS solution provider was able to connect with 5 other VRS solution providers.

2.3.4 In-house Solutions

In addition to vendor-supplied VRS solutions, the VRS network can support in-house solutions built by a manufacturer’s or repackager’s information technology (IT) group. VRS Responders who choose to develop an in-house solution must provide their own Response Gateway dedicated to their use.

LD Gateway functionality will also be required to synchronize LD changes with other VRS solution providers. The LD Gateway can also be developed internally or can be outsourced to a federated VRS solution provider.

No in-house VRS solutions were available for testing during the pilot period.

2.4 Results Verification

2.4.1 Documenting and Automating Verification

To ensure consistency and transparency, rfxcel developed an Excel spreadsheet with formulas that documents and automates the verification of results. This spreadsheet can be provided to other organizations to jump-start their own VRS testing. Below, we describe the columns in the spreadsheet.

Test ID	Test Request	Test Response	Summary Result	Verify Status	Verify Rqrd Flds	Verify Response
VRS01_10	Req : /verify/gtin/10000000000014/lot/LOT_1001/ser/307556349127?context=dscsaSaleableReturn&corrUUID=c052c507-d7c6-4a81-8233-22308845f493&exp=280831&linkType=verificationService&reqGLN=0096295000009	Resp : {"body": {"corrUUID": "c052c507-d7c6-4a81-8233-22308845f493", "data": {"verified": true}, "verificationTimestamp": "2020-03-19T17:20:34.797-05:00", "responderGLN": "0304690000006"}, "status_code": 200}	PASS	PASS	PASS	PASS

- **TEST ID.** Identification code assigned to the test. The spreadsheet also includes a description of the text (not shown).
- **TEST REQUEST.** VRS Request string initiated by rfxcel and passed to the VRS Responder who must process the request string and provide a response on the validity of the PI, which comprises a GTIN, serial number, lot ID, and expiry date.
- **TEST RESPONSE.** Verification response from the VRS Responder. The spreadsheet parses the full text of the response to verify that it meets the HDA and GS1 specifications.
- **SUMMARY RESULT.** Pass/Fail based on the tests performed in the Verify Status, Verify Rqrd Flds (i.e., required fields), and Verify Response columns:
 - **Verify Status:** Verify the status codes returned by the responder (e.g., *status_code:200* or *status_code:400*) based on the expected outcome of the test case.
 - **Verify Rqrd Flds:** Confirm that key required fields are present in the response string (e.g., *verificationTimestamp*, *responderGLN*, *corrUUID*). The required fields are dependent on the test case.
 - **Verify Response:** For responses with a *status_code:200*, verify that a correct response is received in three fields: *verified*, *addInfo*, and *VerificationFailureReason*.

2.4.2 Vantage Responsibilities

To ensure maximum transparency, Vantage independently reviews and monitors the verification spreadsheet and execution of test cases. Specifically, it has the following responsibilities to ensure the integrity of the data and results:

- Review test cases, including request data being sent to each pilot participant.
- Observe engineers who are performing the test queries. This involves each test where requests are sent to all participating VRS vendors.
- Verify raw test response data received for each executed test for each vendor. rfxcel reviews raw data and transfers it to Vantage under appropriate logical and physical security measures. This eliminates the possibility of any data manipulation from the time raw data is generated and Vantage evaluates the results.
- Confirm the accuracy of the spreadsheet used to convert raw data into Pass/Fail results for each test case.
- Review aggregated test data.
- Generate test reports that stipulate whether each test passes or fails. For negative tests that pass, where appropriate, indications will be provided on whether the failure reason is specific or non-specific.
- Issue interim and final reports in conjunction with rfxcel. These reports will summarize test results and provide observations on successful and unsuccessful test cases. They will include recommendations for areas to improve and where potential risks to industry preparedness exist.

2.5 Test Cases

Here we provide the detailed test cases that were executed to verify the readiness of the VRS network. These are the most current HDA test cases that have been developed and approved by VRS Working Group participating in the HDA Round 2 testing, which restarted in the first quarter of 2020.

2.5.1 VRS Request/Response Testing

Table 2. VRS Request/Response Test Case Objectives

Test Case Number	Test Objective
VRS01_10	Verify that a properly formed verification request is successfully processed by the VRS Responder
VRS01_20	Return 400 for non-conforming verification request
VRS02_10	Return 404 for a verification request containing a GTIN that is not in the LD
VRS03_10	Be able to respond to a verification request for scenario 1 (Product matches, no additional information returned)
VRS03_20	Be able to respond to a verification request for scenario 2 (Product matches, Recalled flag returned)
VRS03_30	Be able to respond to a verification request for scenario 3 (Product matches, Suspect flag returned)
VRS03_40	Be able to respond to a verification request for scenario 4 (Product does not match, no reason provided)
VRS04_51	Be able to respond to a verification request for scenario 5 (Product does not match, verification failure reason provided: "No_match_GTIN_Serial")
VRS04_52	Be able to respond to a verification request for scenario 5 (Product does not match, verification failure reason provided),
VRS04_53	Be able to respond to a verification request for scenario 5 (Product does not match, verification failure reason provided: "No_match_GTIN_Serial_Lot")
VRS04_54	Be able to respond to a verification request for scenario 5 (Product does not match, verification failure reason provided: "No_match_GTIN_Serial_Expiry")
VRS_05_00	Verify lot case sensitivity by generating alphanumeric lots with both upper and lower case characters. VRS responder returns negativeVerificationStatus with "No_match_GTIN_Serial_Lot"
VRS_06_00	Verify PI with expiry date value with "00" in DD portion of expiration date. Confirm the verification response treats the "00" as the last day of the month.
VRS_07_00	When an LD record has status=inactive OR deleted, the VRS Solution should not route any verification requests using the LD record
VRS_08_00	When multiple LD records exist for the same GTIN, the verification request's SGTIN's expiration date is used to determine which LD record (ci) to use in routing the request
VRS_09_00	Be able to respond with HTTP status code of 404 to a verification message containing a GTIN that is in the LD but the expiration date in the request is outside the expiration date range for the LD record. This is the scenario where the manufacturer is taking product out of the market.

2.5.2 LD Router Testing

Table 3. LD Router Test Case Objectives

Test Case Number	Test Objective
LD01_10	Verify the ability to receive an LD update for a correctly formatted record owned by an external VRS solution provider. This shows you have connected and can receive data (e.g., certificates are correct).
LD01_20	A correctly formatted record owned by an external VRS solution provider is added correctly to your LD
LD01_30	Ensure that a badly formatted message does not create records in the LD.
LD02_10	Verify the ability to send out an LD update by the LD record’s owner.
LD02_20	Stop a bad record update before you integrate into your own LD.
LD03_10	Verify your ability to ask and retrieve all LD records as of the last modified date owned by the VRS solution provider you are testing against.
LD03_20	Verify the LD records conform to the HDA LD specification.
LD03_30	Verify VRS solution provider rejects non-conforming LD records.
LD04_10	Correctly respond to an LD03_00 request. Send Publishing LD system records created or updated as of the last modified date held in the request message.
LD05_10	When a record is received with status=deleted, the receiving LD should remove the LD record from active listing.
LD06_10	If ownership of a GTIN has changed, you need to know who owns it now and when the previous owner ceded responsibility for it. Therefore, if nextRecordOwner is populated, end expiration date of the record must have a value.
LD07_10	Checks against multiple VRS source systems for LD records with the same GTIN and overlapping startExpDate and endExpDate period. If a GTIN has already been claimed by one VRS solution provider (SOURCE VRS), then you should not overwrite it with another VRS provider’s update.

3 Pilot Results & Observations

In alignment with the pilot approach in Section 2.3, the pilot results are reported in two main subsections, LD synchronization and Request/Response.

Key Test Scenarios for the FDA Pilot

- 1
LD Synchronization: These test cases were designed to verify the ability of VRS solution providers to trade LD updates among all providers. The synchronization testing focused on the ability to *push* and *pull* LD information from different LD providers. A by-product of LD testing is to ensure that VRS solution providers are connected and that master data has been exchanged to support the Request/Response testing described below.

- 2
Request/Response: By merging the pilot with the HDA Round 2 testing, the Request/Response testing will be based on a Many-to-Many testing approach. As part of this approach, rfxcel will still execute One-to-Many Request/Response test cases against connected VRS solution providers to measure their readiness. The One-to-Many results will also be presented to provide additional insight into the readiness of the VRS network.

Results are aggregated to show the general readiness of the VRS network. The following will be used to identify the status of a test case:

Pass	Test case meets the expected outcome as documented in the test case.
Fail	Test case does not match the expected outcome as documented in the test case.
Pending	<p>Test case could not be completed for one of the following reasons:</p> <ul style="list-style-type: none"> Not connected: Connected VRS solution providers are connected to only a subset of the full set. As a result, not all test cases can be executed with all providers. Data not provided: Some test cases require specific data from the test target for completion. Testing cannot be completed without additional data.

3.1 LD Synchronization Test Results

3.1.1 Connection Details

In the first step of testing of the VRS network, the VRS solution provider must connect with other providers to begin the Many-to-Many testing. As we noted above, only VRS solution providers that have connected to at least one other provider will be measured for the pilot.

Figure 3 shows the status of connected VRS solution providers. Requestor F was the only provider that connected to all eight Responder Gateways, while Responder D had the most connections (seven).

Figure 3. Connection Status Matrix

		RESPONDERS									
		A	B	C	D	E	F	G	H	I	
REQUESTORS	A	n/a	N	N	Y	N	Y	Y	Y	Y	5
	B	Y	n/a	N	Y	N	N	N	N	Y	3
	C	Y	N	n/a	Y	Y	Y	Y	N	Y	6
	D	Y	N	Y	n/a	N	Y	Y	N	Y	5
	E	N	N	N	Y	n/a	N	N	N	N	1
	F	Y	Y	Y	Y	Y	n/a	Y	Y	Y	8
	G	Y	N	Y	Y	Y	Y	n/a	Y	Y	7
	H	N	N	N	N	N	Y	N	n/a	N	1
	I	Y	N	Y	Y	N	Y	Y	Y	n/a	6
		6	1	4	7	3	6	5	4	6	
Number of Requestors connected to a Responder											

- n/a = Not Applicable
- Y = Connection made & test data available
- N = Connection not made or test data not available

3.1.2 LD Synchronization Results

Figures 4 and 5 below illustrate the results of the LD testing using the Many-to-Many results from the HDA Round 2 testing. Overall progress remains good. Unlike the Request/Response testing, which can be executed multiple times, LD Synchronization is executed as needed and requires more coordination with other VRS solution providers.

Figure 4. Results of LD Testing (Many-to-Many)



Observations:

- **High pending results.** Four results have higher pending results than average:
 - Test cases LD05_10, LD06_10, and LD07_10 require data with a specific status for testing. This test data requires additional set up and has delayed the ability to fully test.
 - Test case LD01_30 verifies the ability of LD Gateways to correctly handle malformed data. VRS solution providers are designed to prevent malformed data from occurring; as a result, some providers may not be able to generate test data to verify this test case.
- **Failed test cases.** Some test cases logged “Failed” results. The pilot did not assess the cause of failure. The Requestor and Responder are currently troubleshooting the problem.

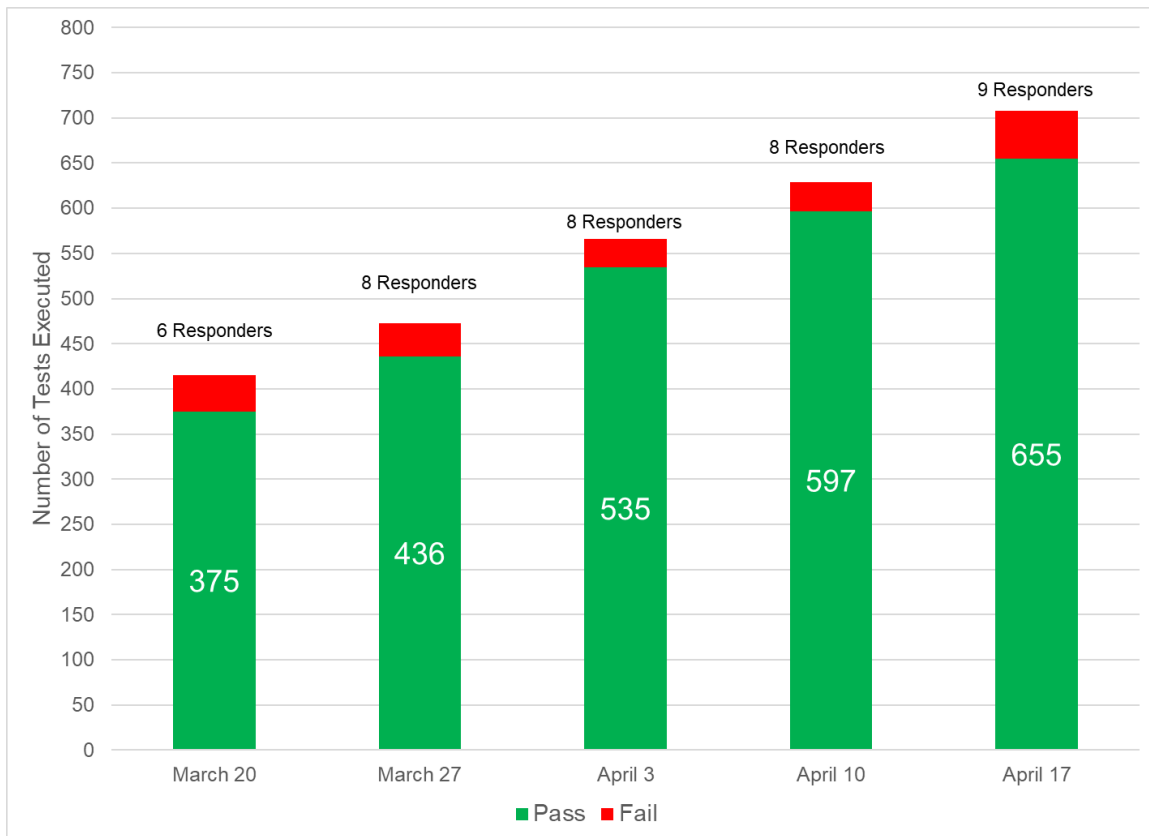
3.2 Request/Response Test Results

3.2.1 Summary Request/Response Results

Figure 5 illustrates the results of connected VRS solution providers from the HDA-sponsored testing using the Many-to-Many approach. The testing period was March 20, 2020, to April 17, 2020. Highlights of the results include:

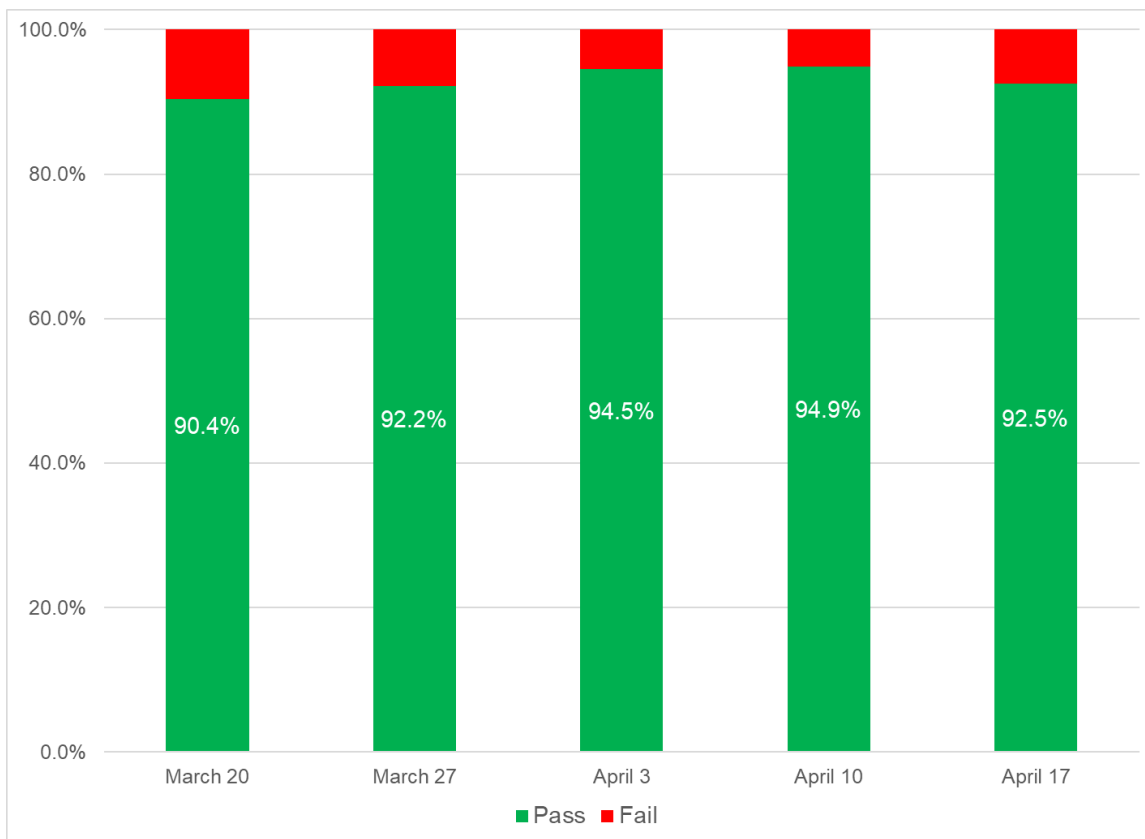
- Increasing readiness.** The *total* number of passed test cases has grown consistently week over week. This is due to new VRS Responders being added to the testing, but is also a reflection of improved readiness. For example, from March 27 to April 10, the number of VRS solution providers did not increase, but the number of passed test cases increased 37 percent, from 436 to 597.
- Increasing VRS Responders.** The number of connected VRS Responders grew 50 percent, from six to nine.

Figure 5. HDA-Sponsored Aggregated Test Results Trend (Many-to-Many)



Pass/fail data show that once connectivity is established, the integrated infrastructure, including the VRS solution providers' software, functions well. As Figure 6 shows, even as new providers gain connectivity, the overall success rate of test cases that can be verified remains high — consistently above 90 percent.

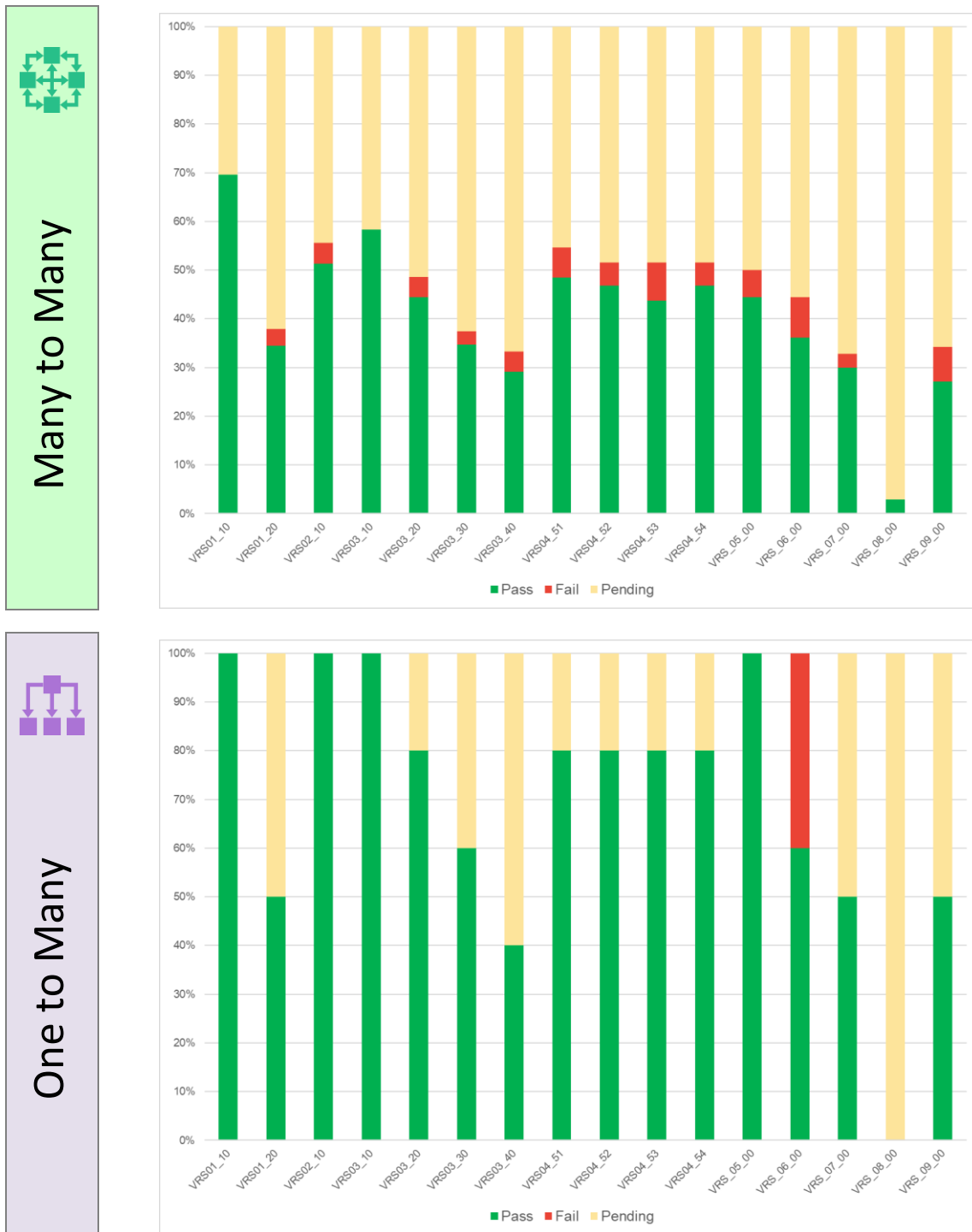
Figure 6. HDA-Sponsored Aggregated Tests Pass/Fail Trend (Many-to-Many)





3.2.2 Detailed Request/Response Results

Figure 7 illustrates aggregated details of the HDA-Sponsored Many-to-Many test results, as well as rfxcel’s One-to-Many test results to give additional insight into the state of the VRS network.

Figure 7. Aggregated Results by Request/Response Test Case as of April 17, 2020



Because this pilot is the first effort to quantify the readiness of the VRS network, there is no benchmark to evaluate progress regarding each test case. It is, however, still important to assess some of the “highs” and “lows” in the testing effort.

	 Many-to-Many	 One-to-Many
High PASS	<p>70% Pass Positive Test Case (VRS01_10): As expected, when presented with a valid PI, most VRS solution providers could pass this test. A smaller percentage, however, are pending confirmation of this due to one of the Pending Items noted above.</p>	<p>100% Pass Positive Test Case (VRS01_10): This may be attributed to rfxcel’s process for failed tests with VRS solution providers. Any failures with the positive are immediately noted with the VRS solution provider and addressed before continuing. The failures are often due to incorrect data used for testing. This process, combined with our automated testing, results in more timely testing/resolution/reporting of issues, which may account for our higher pass rate for the Positive Test Case.</p>
High PENDING	<p>98% Pending for Sold Products (VRS_08_00): This test verifies correct response when verifying a product that has been sold to another manufacturer. This test shows a high pending because the data set-up requires coordination with other VRS solution providers.</p>	<p>100% Pending for Sold Products (VRS_08_00): Like the Many-to-Many test results (98%), rfxcel could not execute this test case because it required additional data.</p>
High Total FAIL	<p>30% of Fails for Invalid PI with Details (VRS04_51, 52, 53, 54): These test cases verified that a Responder could detect an incorrect PI <i>and</i> identify why the verification failed (e.g., wrong serial number, invalid lot). There were 45 fails for this set of test cases (30% of the total failed count).</p> <p>The high failure rate appears to be an issue with how the test cases were written. GS1 specification allows for a failed verification without identifying why. An updated set of test cases has been written to clarify the expected test results and will be executed in the next cycle of Round 2 testing.</p>	<p>0% of Fails for Invalid PI with Details (VRS04_51, 52, 53, 54): Unlike the Many-to-Many test results (30% total failure for this set of test cases), rfxcel shows 0% failure. rfxcel had observed possible confusion in these test cases and accounted for this in our reported test results. This has been clarified in the updated test cases and the failure rate is expected to correct itself.</p>
High Individual FAIL	<p>13% Fail for Expiry Date-00 (VRS_06_00): This test case verifies that Responders can correctly verify an Expiry with a day = “00”. This test case had the highest number of reported failures for any <i>one</i> test case, accounting for 13% of all failed tests.</p>	<p>40% Fail for Expiry Date-00 (VRS_06_00): Although rfxcel’s tests against other VRS solution providers show a higher failure rate than the Many-to-Many tests (13%), this is the one test with the highest failure rate that is consistent with the Many-to-Many test. rfxcel’s higher failure rate can be attributed to our improved ability to test this by converting the positive test case data for this test.</p>

4 Final Observations

This report concludes during a “pause” in the HDA-sponsored testing, as VRS Requestors and Responders update their solutions to align to the new GS1 Messaging Standards published in March 2020. New test cases have already been developed and approved by all providers to account for the new requirements and to make improvements based on the previous test cycle.

In conclusion, rfxcel and Vantage would like the FDA to consider these additional observations.

- **Connectivity criticality.** Maintaining stable connectivity between all VRS solution providers will be critical once the system is fully live. One of the Big 3 wholesale distributors has expressed that connections must remain up, and that any disruptions in connectivity should be “resolved in seconds.” Our experience during this testing cycle has shown this is a challenge. The connectivity issue goes beyond the scope of this pilot and will need further industry assessment.
- **Spirit of participation.** All VRS solution providers in the pilot have shown an openness to work collaboratively with this FDA pilot to ensure that the VRS network is fully tested. For example, two other VRS solution providers performed an in-depth review of the original VRS test cases and made recommendations for improvement. One of these providers shared its unit test cases with the pilot team to further improve the testing methodology. As the pilot moved into the first quarter of 2020, new VRS solution providers joined the testing effort and worked to review/improve the HDA test plans, which are now the basis of the pilot testing.
- **HDA involvement.** The involvement of the HDA was a critical success factor for the pilot and readiness of the VRS network. Its role in the industry provides a focal point for all participants to work together. The actions the HDA took to provide open reporting instilled an added urgency to all VRS solution providers to ensure readiness of their solutions.
- **Many-to-Many is not scalable.** The current Many-to-Many testing effort is the most comprehensive method for ensuring readiness. However, this approach will not scale as more VRS solution providers are added to the network. The pilot testing started with 6 connected VRS solution providers and ended with 9. Another 5 VRS solutions providers are in progress to get connected, bringing the total to 14 VRS solution providers who must test together. Additional VRS solutions (including Inhouse solutions) are expected to join the next cycle of testing. Moreover, once the system is live, this group of VRS solution providers will not be able to provide continued testing to ensure that changes/additions to the VRS network do not introduce new issues.
- **More testing with Requestors.** As testing of VRS Responders continues to show progress, it is important to include Requestors into the test cycles to ensure they can properly interpret all VRS responses. The latest GS1 messaging specifications introduce new scenarios based on industry requests. These scenarios allow for more than one way to flag a failed condition. Requestors will need to make sure they understand these different response scenarios and implement the correct system/operating procedures.

5 Appendix

5.1 Acronyms and Terminology

Table A1 – Acronyms & Terminology

DSCSA	U.S. Drug Supply Chain Security Act
FDA	U.S. Food and Drug Administration
GCP	GS1 Company Prefix
GLN	Global Location Number
GS1	A nonprofit organization that develops and maintains global standards for business communication
GTIN	Global Trade Identification Number
HDA	Healthcare Distribution Alliance
LD	Look-up Directory
PDSA	Pharmaceutical Distribution Security Alliance
PI	Product Identifier
VR	Verification Request
VRS	Verification Router Service
XML	Extensible Markup Language

5.2 FDA Enforcement Delay on Saleable Returns Verification

On September 18, 2019, the United States Food and Drug Administration (FDA) announced that it did not intend to take action against wholesale distributors that do not, prior to November 27, 2020, verify a product identifier prior to further distributing a returned product as required under the DSCSA. This is a 1-year delay in enforcement of this DSCSA requirement.

This announcement does not change the deadline of November 27, 2019, for distributors to comply with the regulation, but indicates that the FDA does not intend to enforce the regulation until 2020. This part of the regulation [section 582(c)(4)(D) of the Federal Food, Drug, and Cosmetic Act, as prescribed by the DSCSA], requires wholesale distributors to verify the product identifier, including the standardized numerical identifier, on each sealed homogeneous case of saleable returned product, or, if such product is not in a sealed homogeneous case, on each package of saleable returned product, prior to further distributing such returned product.

The entire FDA announcement can be found here: www.federalregister.gov/documents/2019/09/24/2019-20651.

Although this enforcement delay should be welcome news to distributors and most companies in the pharmaceutical supply chain, it should not be considered a hiatus from continuing to work toward compliance. As this report indicates, there are still technical challenges to overcome. Each company in the data chain must ensure that its systems are functioning properly — connecting to partners and providing accurate and timely results — well before the FDA begins enforcing the requirement. Time and resources needed to resolve issues will become more and more constrained as the enforcement date approaches. Pausing or waiting to complete the tasks at hand can be risky.

5.3 Original FDA Pilot Test Cases

For completeness, this section provides the original test cases that were used to start this FDA Pilot effort. Since the HDA has restarted their coordinated testing efforts in Q1-2020, this FDA Pilot has chosen to adopt those new test cases to help accelerate the total testing between VRS solution providers.

Table A2 - VRS Original Test Case Descriptions

HDA Test ID	Test Case Name	Test Case Description Expected Results in “verified” and “verificationFailureReason” fields	Comments / Test Conditions
n/a	RR-POS-01 Verify positive response received for a valid PI	“true” & no failure reason provided	The positive test case is intended to verify the following HDA test cases: 03, 04, 07, 08, 09. These are summarized below. PIs are provided by each VRS Solution.
03	VRS Solution: Process verification request (VR) and route to responders’ VRS solution providers	Submit the verification request to the responder’s VRS based on either Global Trade Identification Number (GTIN) or GS1 Company Prefix (GCP) in the look-up directory.	
04	VRS Solution: Process VR and route to responder	Submit the verification request to the appropriate responder’s repository based on either GTIN or GCP in the LD.	
07	Responder: Response to the VR request	Responder provides reply to VRS indicating whether the PI provided in the VR are valid	
08	Routing of the response to a VR between two VRSS	VR response routed to the requestor’s VRS from the responder’s VRS, as the responder elects to interact with a single VRS Solution that is different from the requestor’s VRS Solution	
09	Requestor: Receive response to VR from VRS Solution	VRS Solution provides response for the VRs received from the responder to the requestor	
N/A	RR-FAIL-01 GTIN, Serial Number does not match VRS responder data	Specific: “false” & “No_match_GTIN_Serial” Non-Specific: “false” & “No_reason_provided” No match between GTIN and Serial Number (for a serialized product, if GTIN and Serial Number do not match, there is no need to check whether Lot or Expiry also match)	This GS1 standard supersedes the original HDA “verifiedInfo” code 001. Negative test condition will be triggered by passing the text “INVALID” instead of the expected Serial Number.
N/A	RR-FAIL-02 GTIN, Serial Number, Lot does not match VRS responder data	Specific: “false” & “No_match_GTIN_Serial_Lot” Non-Specific: “false” & “No_reason_provided” No match between (GTIN and Serial Number) and Lot Number	This GS1 standard supersedes the original HDA “verifiedInfo” code 002. Negative test condition will be triggered by passing the text “INVALID” instead of the expected Lot ID.
N/A	RR-FAIL-03a GTIN, Serial Number, Expiry Date does not match VRS responder data	Specific: “false” & “No_match_GTIN_Serial_Expiry” Non-Specific: “false” & “No_reason_provided” No match between (GTIN and Serial Number) and Expiry Date	This GS1 standard supersedes the original HDA “verifiedInfo” code 003. Negative test condition: Pass the unused date “300531” instead of the expected date
N/A	RR-FAIL-03b GTIN, Serial Number, Expiry Date does not match VRS responder data	Specific: “false” & “No_match_GTIN_Serial_Expiry” Non-Specific: “false” & “No_reason_provided” No match between (GTIN and Serial Number) and Expiry Date	This GS1 standard supersedes the original HDA “verifiedInfo” code 003. Negative test condition: Pass malformed date “200230”

HDA Test ID	Test Case Name	Test Case Description Expected Results in "verified" and "verificationFailureReason" fields	Comments / Test Conditions
N/A	RR-FAIL-04 GTIN, Serial Number, Lot, Expiry Date does not match VRS responder data	Specific: "false" & "No_match_GTIN_Serial_Lot_Expiry" Non-Specific: "false" & "No_reason_provided" No match between (GTIN and Serial Number) and Lot Number and Expiry Date	This GS1 standard supersedes the original HDA "verifiedInfo" code 004. Negative test condition will be triggered by passing the following: <ul style="list-style-type: none"> • Test "INVALID" for the expected Lot ID • Test "300531" for the expected Expiry
N/A	RR-FAIL-05a GTIN does not belong to the VRS responder and no alternative LD owner exists in the LD router service.	This is a unique condition and will leverage the HTTPS error response codes to indicate failure: 404	Negative test will be triggered by: GTIN="12345678901234" (valid format but invalid GTIN)
N/A	RR-FAIL-05b GTIN does not belong to the VRS responder and no alternative LD owner exists in the LD router service.	This is a unique condition and will leverage the HTTPS error response codes to indicate failure: 404	Negative test will be triggered by: GTIN="1234567890123" (valid format < 14 digits)
N/A	RR-FAIL-05c GTIN does not belong to the VRS responder and no alternative LD owner exists in the LD router service.	This is a unique condition and will leverage the HTTPS error response codes to indicate failure: 404	Negative test will be triggered by: GTIN="123456789012345" (valid format > 14 digits)

5.4 VRS Request/Response Test Case Detailed Descriptions

Table A3 - VRS Request/Response Test Case Descriptions

Test Case Number	Test Objective	Correct Behavior	References
LD01_10	Verify the ability to receive an LD update for a correctly formatted record owned by an external VRS Solution. This shows you have connected and can receive data (certificates etc. are correct)	Inbound message arrives in your system	API calls should confirm to the Verification Router Service (VRS) LD Technical Specifications R1.10. A VRS Solution should follow R-012 in the VRS Revised ATP Requirements for building out the connections to other VRS solution providers.
VRS01_10	Verify that a properly formed verification request is successfully processed by the VRS responder	VRS responder receives VRS request and returns HTTP status code 200	GS1 Lightweight Messaging Standard for Verification of Product Identifiers R1.1 July 2019
VRS01_20	Return 400 for non-conforming verification request.	VRS responder rejects the malformed VRS request message and returns HTTP status code 400	GS1 Lightweight Messaging Standard for Verification of Product Identifiers R1.1 July 2019
VRS02_10	Return 404 for a verification request containing a GTIN that is not in the Lookup Directory.	VRS responder returns HTTP status code 404 to the requestor to convey that GTIN in the request does not match any of the LD record	
VRS03_10	Be able to respond to a verification request for scenario 1	VRS responder receives and processes VRS request, finds record matching PI and returns positiveVerificationStatus without additionalInfo value as specified by Scenario 1(Product matches, no additional information returned). Section 8.3, 8.4"	GS1 US Implementation Guideline - Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Returned Product Identifiers R1.0"
VRS03_20	Be able to respond to a verification request for scenario 2	VRS responder receives and processes VRS request, finds record matching PI and returns positiveVerificationStatus with "Recalled" as additionInfo as specified by Scenario 2 (Product matches, Recalled flag returned). Section 8.3, 8.5"	GS1 US Implementation Guideline - Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Returned Product Identifiers R1.0"
VRS03_30	Be able to respond to a verification request for scenario 3	VRS responder receives and processes VRS request, finds record matching PI and returns positiveVerificationStatus with "Suspect" as additionInfo as specified by Scenario 3 (Product matches, Suspect flag returned). Section 8.3, 8.6"	GS1 US Implementation Guideline - Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Returned Product Identifiers R1.0"
VRS03_40	"Be able to respond to a verification request for scenario 4	VRS responder receives and processes VRS request. VRS responder does not find a record matching PI and returns negativeVerificationStatus with "No_reason_provided" for verificationFailureReason as specified by scenario 4 (Product does not match, no reason provided). - "No_reason_provided" Section 8.3, 8.7"	GS1 US Implementation Guideline - Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Returned Product Identifiers R1.0"
VRS04_51	"Be able to respond to a verification request for scenario 5 (Product does not match, verification failure reason provided)	VRS responder receives and processes VRS request. VRS responder does not find a record matching PI and returns negativeVerificationStatus with "No_match_GTIN_Serial" for verificationFailureReason as specified by scenario 5 (Product does not match, verification failure reason provided). Section 8.3, 8.8"	GS1 US Implementation Guideline - Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Returned Product Identifiers R1.0"

Test Case Number	Test Objective	Correct Behavior	References
VRS04_52	"Be able to respond to a verification request for scenario 5 (Product does not match, verification failure reason provided),	VRS responder receives and processes VRS request. VRS responder does not find a record matching PI and returns negativeVerificationStatus with "No_match_GTIN_Serial_Lot" for verificationFailureReason as specified by scenario 5 (Product does not match, verification failure reason provided). Section 8.3, 8.8"	GS1 US Implementation Guideline - Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Returned Product Identifiers R1.0"
VRS04_53	"Be able to respond to a verification request for scenario 5 (Product does not match, verification failure reason provided).	VRS responder receives and processes VRS request. VRS responder does not find a record matching PI and returns negativeVerificationStatus with "No_match_GTIN_Serial_Lot_Expiry" for verificationFailureReason as specified by scenario 5 (Product does not match, verification failure reason provided). Section 8.3, 8.8"	GS1 US Implementation Guideline - Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Returned Product Identifiers R1.0"
VRS04_54	"Be able to respond to a verification request for scenario 5 (Product does not match, verification failure reason provided).	VRS responder receives and processes VRS request. VRS responder does not find a record matching PI and returns negativeVerificationStatus with "No_match_GTIN_Serial_Expiry" for verificationFailureReason as specified by scenario 5 (Product does not match, verification failure reason provided). Section 8.3, 8.8"	GS1 US Implementation Guideline - Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Returned Product Identifiers R1.0"
VRS_05_00	Verify lot case sensitivity by generating alphanumeric lots with both upper and lower case characters.	VRS responder receives, processes VRS request and does not find a record matching PI whose lot number contains alphanumeric value with mix upper and lower case. VRS responder returns negativeVerificationStatus with "No_match_GTIN_Serial_Lot" for verificationFailureReason as specified by scenario 5 (Product does not match, verification failure reason provided).Section 8.3, 8.8"	GS1 US Implementation Guideline - Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Returned Product Identifiers R1.0"
VRS_06_00	Verify PI with expiry date value with "00" in DD portion of expiration date. Confirm the verification response treats the "00" as the last day of the month.	VRS responder receives a verification request with an expiry date parameter value that contains a "00" in day portion. As described in section 2 of the GS1 US Implementation Guideline - Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Returned Product Identifiers R1.0, the responder derives the expiry date parameter by converting the expiry parameter value to represent the last day of the month and year of the expiry date parameter. VRS responder finds a record matching the GTIN, Serial Number, Lot and derived expiry date, and returns positiveVerificationStatus without additionalInfo value as specified by Scenario 1(Product matches, no additional information returned).Section 8.3, 8.4	GS1 US Implementation Guideline - Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Returned Product Identifiers R1.0
VRS_07_00	When an LD record has status=inactive OR deleted, the VRS Solution should not route any verification requests using the LD record.	VRS responder receives a request for a GTIN whose matching LD record has a status of either inactive or deleted. Per section 9 of the implementation guideline, VRS responder returns HTTP status code 404 to the requestor to convey that GTIN in the request does not match any of the LD record.	GS1 US Implementation Guideline - Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Returned Product Identifiers R1.0

Test Case Number	Test Objective	Correct Behavior	References
VRS_08_00	When multiple LD records exist for the same GTIN, the verification request's SGTIN's expiration date is used to determine which LD record (ci) to use in routing the request.	VRS responder receives a request for a GTIN with multiple active LD records matching the GTIN. VRS responder routes the VRS request message to the sourceVRS in the LD record matching the GTIN and expiry date withing the LD startExpDate and endExpDate period.	Verification Router Service (VRS) LD Technical Specifications R1.10
VRS_09_00	Be able to respond with HTTP status code of 404 to a verification message containing a GTIN that is in the Lookup Directory but the expiration date in the request is outside the expiration date range for the LD record. This is the scenario where the manufacturer is taking product out of the market.	VRS responder receives a request for a GTIN with the expiryDate in the PI that falls outside the startExpDate and endExpDate period defined in the LD. Per Section 9 of the implementation guideline, VRS responder returns HTTP status code 404 to the requestor to convey that GTIN in the request does not match any of the LD record	"GS1 US Implementation Guideline for Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Returned Product Identifiers, Section 9

Table A4 - LD Router Test Case Descriptions

Test Case Number	Test Objective	Correct Behavior	References
LD01_10	Verify the ability to receive an LD update for a correctly formatted record owned by an external VRS Solution. This shows you have connected and can receive data (certificates etc. are correct)	Inbound message arrives in your system	API calls should confirm to the Verification Router Service (VRS) LD Technical Specifications R1.10. A VRS Solution should follow R-012 in the VRS Revised ATP Requirements for building out the connections to other VRS solution providers.
LD01_20	A correctly formatted record owned by an external VRS Solution is added correctly to your LD	Inbound message arrives and is added to your LD	
LD01_30	Ensure that a badly formatted message does not create records in the LD	Inbound message arrives but is rejected	
LD02_10	Verify the ability to send out an LD update by the LD record's owner.	the changes made in the publishing LD should be reflected in the subscribing LDs	API calls should confirm to the Verification Router Service (VRS) LD Technical Specifications R1.10. A VRS Solution should follow R-012 in the VRS Revised ATP Requirements for building out the connections to other VRS solution providers.
LD02_20	Stop a bad record update before you integrate into your own LD	Subscribing LD should reject the incorrectly formatted LD record from the source LD	
LD03_10	Verify your ability to ask and retrieve all LD records as of the last modified date owned, by the VRS Solution you are testing against.	Receive the LD records from testing partner that have occurred as of the Last Modified date	API calls should confirm to the Verification Router Service (VRS) LD Technical Specifications R1.10. A VRS Solution should follow R-012 in the VRS Revised ATP Requirements for building out the connections to other VRS solution providers.
LD03_20	Verify the Lookup Directory records conform to the HDA Lookup Directory specification.	The conforming LD record additions and updates since the last modified date from the publishing LD system are appropriately reflected in the subscribing LD system	
LD03_30	Verify VRS Solution rejects non-conforming LD records.	The subscribing LD system should reject syntactically incorrect LD records retrieved from the LD publisher	
LD04_10	Correctly respond to an LD03_00 request	send Publishing LD system records created or updated as of the last modified date held in the request message	API calls should confirm to the HDA Lookup Directory specification. A VRS Solution should follow R-012 in the VRS Revised ATP Requirements for building out the connections to other VRS solution providers.
LD05_10	When a record is received with status=deleted, the receiving Lookup Directory should remove LD record from active listing.	LD record marked with status = deleted is removed from the LD subscribing system	API calls should confirm to the Verification Router Service (VRS) LD Technical Specifications R1.10.
LD06_10	If ownership of a GTIN has changed you need to know who owns it now and when the previously owner ceded responsibility for it. Therefore, if nextRecordOwner is populated, end expiration date of the record must have a value.	Confirm that both endExpDate and nextRecordOwner are populated with values for the specific GTIN LD test record targeted to reflect ownership change	
LD07_10	Checks against multiple VRS source systems for LD records with the same GTIN and overlapping startExpDate and endExpDate period. If a GTIN has already been claimed by one VRS Solution (SOURCE VRS) then you should not overwrite it with another VRS's update.	Subscribing LD should flag and return a warning upon detection of LD records with different sourceVRS values with same GTIN and overlapping startExpDate and endExpDate period.	

5.5 About the Authors



Founded in 2003, rfxcel is one of the first companies to focus on the safety of the pharmaceutical supply chain and bring advanced track and trace software to manufacturers, repackagers, wholesalers, distributors, and dispensers. rfxcel's mission is to be the thought leader in traceability technology and to enable customers to better manage their business today and deliver value tomorrow. www.rfxcel.com.



Vantage Solutions is a manufacturing productivity company celebrated its 25th anniversary in 2019. For manufacturers facing safety, quality, or efficiency challenges, the company provides strategic guidance and cost-effective execution of initiatives to improve serialization, packaging, inspection, and more. Vantage's team is seasoned, lean, on-time, and operates within your budget. www.vantage-cg.com.