

Out of Specification (OOS) Retesting Procedure

ChromaDex offers an Out of Specification (OOS) retesting procedure allowing our clients the option to have their samples retested when they do not meet the expected specifications. This ChromaDex Tech Tip outlines our OOS retest policy and procedure. Please note the OOS Procedure does not apply to stability studies. If you have any questions about this or other aspects of our analytical services, please contact your ChromaDex Technical Sales Representative.

Submitting Samples and Including Specifications

ChromaDex requires a completed sample submission form (SSF) for all samples submitted to our laboratory for analysis. Please see the Sample Submission Tech Tip #0008 for further details. Included in the SSF, there is a section for sample specifications.

CONTACT INFORMATION		SAMPLE SUBMISSION ADDRESS	PLEASE READ THESE INSTRUCTIONS BEFORE FILLING OUT THIS FORM AND SHIPPING SAMPLES:									
Company Name: _____ Cust ID: _____		ChromaDex Analytics Attn: Sample Management 2830 Wilderness Pl. Boulder, CO 80301	1. Please contact a ChromaDex Representative at (949) 419-0288. 2. Fill out this form completely with payment information and fax to (949) 419-0294. 3. If your samples exceeds five, please attach the Sample Submission Addendum.									
Contact Name: _____												
Contact Phone #: _____ Contact Fax #: _____		PAYMENT ADDRESS ChromaDex, Inc. Attn: Accounts Receivable 10035 Highlands Blvd., Suite G Irvine, CA 92618 Tel: (949) 419-0288 Fax: (949) 419-0294	CREDIT CARD DETAILS (if paying by credit card)									
Report Address: _____ Invoice Address: _____			AMEX <input type="checkbox"/> MC <input type="checkbox"/> VISA <input type="checkbox"/> Name on Card: _____ Card Number: _____ Expiration Date: _____									
Report Emails: _____ Invoice Emails: _____												
SAMPLE INFORMATION			ANALYSIS INFORMATION									
SAMPLE IDENTIFICATION	LOT #	→ CIV USE ONLY	ASSAY	PART NUMBER	SPECIFICATIONS LOWER AND UPPER LIMITS W/UNITS	SERVING SIZE	HIGH PURITY MTL	SOFT FILL WEIGHT	REPORT TYPE* (ARS or ATR)	TURN AROUND TIME** (10, 5, 3 days or Other)	PRICE PER SAMPLE	FOR CDXA USE ONLY
Total Samples to be tested: _____ Storage Conditions: _____			Note: Delayed results may occur when specifications information is not provided or is given inaccurately.									
*REPORT INFORMATION				SPECIAL INSTRUCTIONS (add any comments that may help in the processing of your samples)								
Analytical Result Sheet (ARS): 1 page summary report, results only Analytical Test Report (ATR): Full report, includes methods, data details, and chromatograms.												
For more information about these report types and their associated fees, please call (949) 419-0288. If report is not indicated, an ARS will be assigned.												
**TURN AROUND TIME												
10 Working Days: Standard, 5 Working Days: List price x2, 3 Working Days: List price x2.5, 1 Working Day: Please call for pricing												
Note: Turn around times for analyses will begin the day after sample and signed sample submission form have been received by the testing facility. If no turn around time is selected, 10 working days will be assigned. *Turn around time is based on industry accepted methods and procedures being available for the material or chemical to be tested. If additional method development or research is required, turn around times may be affected.												
CLIENT AUTHORIZATION (please sign to confirm services, pricing, and terms noted on this form, as an authorized Representative of the company referenced above)												
Authorized by (Client): _____		Signature: _____		Date: _____		Purchase Order #: _____						
Received by (ChromaDex): _____		Signature: _____		Date: _____		Work Order #: _____						
<small>Terms: Due upon delivery of completed results, with an approved ChromaDex credit account. All work is subject to our standard Terms and Conditions for Purchase and Sale of ChromaDex Products and/or Services, a copy of which has been provided by the Company and is incorporated herein by this reference. Samples may be sub-contracted at the discretion of the laboratory. Rev: 01/2012</small>												



Sample specifications are always requested and encouraged by ChromaDex, however it is not required. Specifications guide our laboratory in the proper preparation of customer samples which allows us to function efficiently, minimize rework, and meet turn around times. If specifications are not provided and the material does not meet expected quality, the OOS retest option is not available to the customer.

Out of Specification (OOS) Retesting Procedure

Out of Specification Data

When a sample result does not meet the specification listed on the SSF, a formal investigation is initiated by ChromaDex. The trigger for initiation of the investigation is dependent on the format of specification provided. Below are the specification formats typically used and the types of results that will prompt an investigation. For purposes of the OOS trigger, the result is rounded to the same number of significant figures as listed in the specification that was entered on the SSF.

Specification Example	Format Type	OOS Trigger
20.0%	Flat Value	Results outside of $\pm 10\%$ of this specification prompt an OOS investigation. For example, any results $< 18.0\%$ or $> 22.0\%$ will prompt an OOS investigation in this case.
20%	Flat Value	Results outside of $\pm 10\%$ of this specification prompt an OOS investigation. Since there are only 2 significant figures in the specification given, the result is rounded to the same two significant figures before deciding to initiate the OOS investigation. For example, any results $\leq 17.4\%$ or $\geq 22.5\%$ will prompt an OOS investigation in this case.
20.0%-25.0%	Specific Range	Specific ranges are those that include three or more significant figures. If a result falls outside of the exact range specified an OOS investigation is conducted. For example if results of 19.9% are posted for this sample an OOS investigation is conducted since rounding does not apply in this situation.
20%-25%	General Range	Results outside of this range will prompt an OOS investigation. For example, any results $\leq 19.4\%$ or $\geq 25.5\%$ will prompt an OOS investigation in this case.
$\geq 97\%$	Greater Than Value	Greater than results are not subject to rounding. Any value that is below the given "greater than" specification is a result that will prompt an OOS investigation. For example, if a result of 96.9% is posted for a sample with the specification of $\geq 97\%$ then an OOS investigation will be conducted for this analysis.
$\leq 20\%$	Less Than Value	Similar to "greater than", "less than" results are also not subject to rounding. A result of 20.1% would initiate an OOS investigation in this case.
25mg/serving	Serving Size Value	Serving size specifications will follow the rounding and significant figure rules as seen with flat value, general range and specific range specifications. Please refer to the above sections for guidance.

Out of Specification (OOS) Retesting Procedure

OOS Investigations

Once it is determined by ChromaDex that an OOS investigation is required, there are several procedures that are followed to ensure the data reported is valid. These procedures include the following:

- Confirm that the Laboratory Control Sample (LCS)/Negative Control are within expected limits.
- Confirm that no documentation errors occurred during the reporting and data collection process (i.e. calculation/transcription).
- Confirm the correct SOP was followed with no deviations (if deviations did occur, it must be described on the OOS report form).
- Check the preparation of sample(s), reagents and reference standard solutions (concentrations, purity, sterility and glassware used) to insure they were prepared properly.
- Check to confirm that the balance used was properly calibrated for the day that the sample was prepared.
- Confirm that the analytical instrument used performed as expected (i.e. calibrations are as expected, ConCal passed and instrument parameters are as expected).
- If applicable, inspect the autosampler vials and verify that the vial septum has not been compromised.
- Confirm the results of other samples in the same sequence if batching has occurred.

If after the above procedures have been completed and there is reason to believe that there is an error, then the data gathered will be invalidated and the sample will be rerun. If the OOS investigation indicates there is no reason to suspect analyst or procedural error, then an OOS investigation report is generated and included in the analysis report that is supplied to the customer. Examples of these reports can be found on the right.

Analysis Report

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Analytical Results Sheet

Customer: Address (City, State):	Clive Leaf Export	Report Number: Report Number:	
Sample Name: Sample Lot: CDXA Number:	CDXA-11-0281	Date Received: Purchase Order:	24 May 11
Assay: Part Number: Method:	Chlorophyll by HPLC Water Content by LOD CDXA-00100362-ARS CDXA-00100130-ARS 99-1-CD-2.0-000209 99-1-CD-1.2-000104	Date of Report: Page: Test Location:	3-Jun-11 1 of 1 Seaside, CO

Analyte	Units	Spec.	Result	Reporting Limit
Chlorophyll (dried basis)	%	225	18.5	
Water Content	%	4.0	1.80	

Verified: Paul Barton Approved: _____ Signed on for file at CDXA

This product analysis is subject to our "Standard Terms and Conditions for the Purchase and Sale of Chromadex Products and/or Services." If any of which has been printed to our client and is incorporated herein by this reference. Any more specifically set forth herein. This product analysis is for the benefit of our client only. It may not be relied upon by any other party without our prior written consent. Results shown in this report, provided to us by our client and modified cannot be applied to any other material or sample.

ND = Not Detected
BRL = Below reporting limit (compound detected below BRL)

OOS Investigation Report

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Form 1A: Initial Investigation of Out of Specification (OOS) Results

Customer: Sample: Sample Name: Lot/ID#	CDXA-11-0281 Clive Leaf Export CDXA-11-0281	Date: Assay: Part Number: Method:	3-Jun-11 Chlorophyll HPLC CDXA-00100362-ARS 99-1-CD-2.0-000209
Analyst: Reviewed:	Paul Barton	Reviewed:	Paul Barton

OOS Result: 18.5%
Specification: 225%

Investigation Summary:
The OOS investigation should be conducted by the analyst and the analyst manager or group leader. If there is any reason to suspect the data, document the reason, review, investigate the cause and report the analysis.

Checklist	Yes	No	Comments
Subsidiary Control Sample (LCS) within limits	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Methodology	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Instrumentation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Methodology	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Standard Stock (SP)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Standard, Services, Pipettes	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Order of Operations Used	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Check-Balance Calibration Performed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Reference	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Calibration OK	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Continuing Calibration Passed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Post-plant Parameters OK	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

Comments:
No data and/or method, analyst/analyst?
Sample duplicate was prepared. All 6 results are consistent and within spec.

Investigation Summary:
Investigation Summary:
If there is no reason to suspect the analysis with the analyst manager will sign below. This form will be used to file the report for the client and the analyst manager, to sampling, and retesting.

Manager/Analyst:
Signature: _____
Date: _____

Analyst:
Signature: _____
Date: _____

Client/Analyst:
Signature: _____
Date: _____

CDXA Order: _____

This document is the property of Chromadex, Inc. and is confidential information and is not to be distributed outside of the client's organization. This document has a digital signature of the analyst.

Out of Specification (OOS) Retesting Procedure

ChromaDex® OOS Rerun Policy

ChromaDex offers a way to quickly re-submit an OOS sample for further confirmation of OOS results if so desired by reanalysis of the sample in question.

At the bottom of each OOS investigation report there is a section for client authorization and PO number. The PO number used can be the same as on the original SSF submitted if desired. If a customer wishes to obtain further data to confirm that the OOS result is reproducible and/or valid, these two sections should be completed and the form submitted to the ChromaDex sales department.

Upon customer authorization, a rerun of the retained sample will be conducted and reported under a new order. For all OOS reruns, the turnaround time will automatically default to 5 days (day 1 is the day after the complete signed OOS report has been received by ChromaDex). Furthermore, the sample will be prepared and run in duplicate so as to ultimately provide three data points for overall comparison of results.

If the data from the OOS rerun confirms the out of specification result originally posted, the customer will be charged for the list price of a normal 10 day TAT for that particular analysis. Although a 5 day TAT is assigned, the normal rush price is not charged.

If after the OOS retest has been completed the result meets specification, the original report is invalidated, a separate report will list the new results with information regarding the assignable cause, and the customer will not be charged for the retest. The report to the right is an example of a customer authorized OOS rerun when the rerun result met the specification.



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Form 2: OOS Retest Form (w/Assignable Cause)

Sample Info:
 Customer: MCT5
 Date: 5-Jan-11
 Sample Name: MCT5
 OOS #:
 Lot Number:
 Analyt: Fat% Acid (TMS) by GC
 Orig. OOS #:
 Part Number: 00A-0013022-A-MS
 Retest OOS #:
 Method: 99-1-CD-5-3-000002
 Retest OOS #:
 Analyt: Fat% Acid
 Review: Paul Stottum

OOS Result:	86.4 %
Specification:	70 - 82 %

Retesting Results

Original Result:	86.4 %
Retest Result # 1:	41.9 %
Retest Result # 2:	40.8 %

Do the retest results confirm original OOS result? (Y/N)
 If Yes, Skip the rest of Form 2 and report all three results.
 If No, report both retest results, invalidate the original result, and investigate root cause of the original result on this form.

Assignable Cause
 Investigate the original data and determine an assignable cause per ICH Q10 Root Cause Analysis
 We exceeded the Internal Standard and the cause of the problem is a new Fat% Acid Standard run and internal standard was prepared. New sample preparations were run under new standard?

Does the assignable cause require a corrective action/preventive action? If so, describe action plan and document action per the Corrective Action/Preventive Action (CAPA):
 N/A

Laboratory Manager/Designer Signature: _____ Date: _____
 QA Signature: _____ Date: _____

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