ChromaDex®

Tech Tip 0021

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.

ChromaDex® **Sample Submission Form**

CONTACT INFORMATION

Company Name:	Cust ID:
Contact Name:	
Contact Phone #:	Contact Fax #:
Report Address:	Invoice Address:
Report Emails:	Invoice Emails:

SAMPLE SUBMISSION ADDRESS

ChromaDex Analytics
Attn: Sample Management
2830 Wilderness Pl.
Boulder, CO 80301

PAYMENT ADDRESS

ChromaDex, Inc.
Attn: Accounts Receivable
10005 Muirlands Blvd., Suite G
Irvine, CA 92618
Tel: (949) 419-0288
Fax: (949) 419-0294

PLEASE READ THESE INSTRUCTIONS BEFORE FILLING OUT THIS FORM AND SHIPPING SAMPLES:

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.

CREDIT CARD DETAILS (if paying by credit card)

AMEX ☐ MC ☐ VISA ☐

Name on Card:

Card Number:

Expiration Date:

SAMPLE INFORMATION / **ASSAY INFORMATION**

SAMPLE IDENTIFICATION	LOT #	→ CDX USE ONLY	ASSAY	PART NUMBER	SPECIFICATIONS LOWER AND UPPER LIMITS W/UNITS	SERVING SIZE	HIGH PURITY RAW MTL. ✓	SOFT FILL WEIGHT ✓	REPORT TYPE* (ARS or ATR)	TURN AROUND TIME** (10, 5, 3, 1 days or Other)	PRICE PER SAMPLE	FOR CDXA USE ONLY

Specifications Column

Total Samples to be tested: _____ Storage Conditons: _____

Note: Delayed results may occur when specifications information is not provided or is given inaccurately.

***REPORT INFORMATION**

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.

SPECIAL INSTRUCTIONS (add any comments that may help in the processing of your samples)

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 #:

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

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 ±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 ±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 ≤17.4% or ≥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 ≤19.4% or ≥25.5% will prompt an OOS investigation in this case.
≥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 ≥97% then an OOS investigation will be conducted for this analysis.
≤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.

10005 Muirlands Blvd., Suite G • Irvine, CA 92618 • Ph: +1-949-419-0288 • Fx: +1-949-419-0294
Em: sales@chromadex.com • www.chromadex.com

Out of Specification (OOS) Retesting Procedure

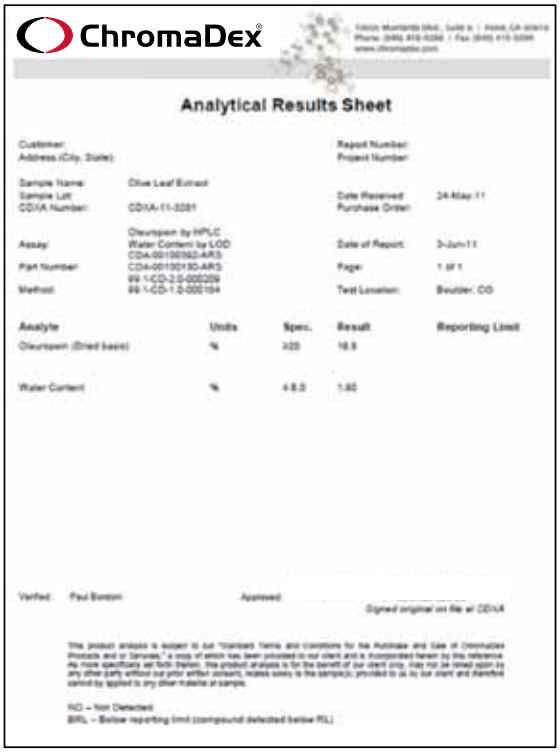
OOS Investigations

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.

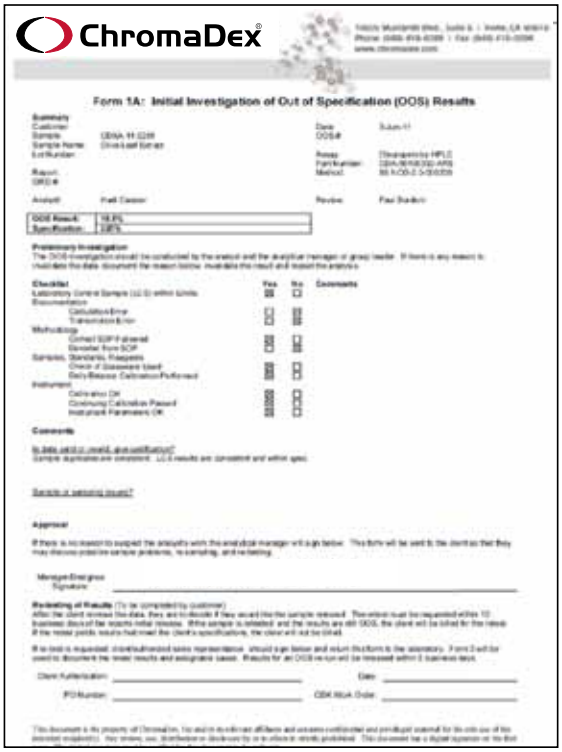
If after the above procedures have been completed and there is reason to believe that there is an error, then the data gathered will be invalidated and the sample will be rerun. If the OOS investigation indicates there is no reason to suspect analyst or procedural error, then an OOS investigation report 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


ChromaDex

Analytical Results Sheet

OOS Investigation Report


ChromaDex

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

10005 Muirlands Blvd., Suite G • Irvine, CA 92618 • Ph: +1-949-419-0288 • Fx: +1-949-419-0294
Em: sales@chromadex.com • www.chromadex.com

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.

ChromaDex

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

Please contact a ChromaDex® Representative with any questions about our products and services.

10005 Muirlands Blvd., Suite G • Irvine, CA 92618 • Ph: +1-949-419-0288 • Fx: +1-949-419-0294
Em: sales@chromadex.com • www.chromadex.com