
VECTRA[®] DA CLINICAL STUDY SAMPLE COLLECTION, HANDLING AND SHIPPING GUIDELINES

This document offers some basic guidelines to follow when collecting and handling human serum samples intended for submission to Myriad RBM for Vectra DA testing at Crescendo Bioscience for use in clinical trials.

Following these guidelines will help ensure that submitted samples are uniformly handled in an optimum fashion to minimize the influence of preanalytical variables.

RECOMMENDED MATERIALS

It is necessary to have the proper materials ready when collecting, storing and shipping the specimens for your study. The materials and supplies listed here are recommendations only.

- BD SST[™] transport tube (7.5mL SST tube, 16x100 BD367987) or equivalent
- Axygen Cyro-Vials (Axygen #SCT-200-SS-C) or equivalent
- Axygen SCO-C-S caps (clear, sterile screw caps with “o” rings)
- Temperature-controlled centrifuge
- -80 °C freezer
- If a -80 °C freezer is not available, then the samples should be stored at as low a temperature as possible. If stored at -20 °C the freezer should not be a frost free type. Sample stability has not been assessed at temperatures higher than -70 °C.
- Dry ice
- Various packing supplies as required
- Styrofoam-insulated corrugated fiberboard outer packaging containers

COLLECTION PROCEDURE

Serum

Samples should be collected in plastic BD SST transport tube (7.5mL SST tube, 16x100 BD367987) or equivalent. Following collection, the samples should be inverted gently 5 times and allowed to clot in the collection tubes for a minimum of 30 minutes at room temperature. Serum should be separated from the clot by centrifuging the collection tube for 15 minutes between 1,100 - 1,300 xg (or according to the manufacturer’s instructions) using a temperature setting of 20-25 °C, within two hours of collection. The serum should be aspirated by pipette, aliquoted and stored in Axygen Cyro-Vials (Axygen #SCT-200-SS-C) or equivalent.

Samples requiring both Vectra DA and Myriad RBM testing services require two separate aliquots shipped per sample. Samples must be clearly designated for the service to be performed (Vectra DA or Myriad RBM services).

The minimum sample volume requirement for Vectra DA testing is 300 µL of serum per sample.

RECOMMENDED STORAGE REQUIREMENTS

All samples should be frozen immediately after collection and processing (at -80 °C or on dry ice if possible). It is recommended that samples be stored at -80 °C. If samples are not frozen immediately, they may be stored at 2-8 °C prior to freezing for no longer than 96 hours. If samples are stored at -20 °C for a few weeks, the freezer must be of a NON frost-free type. Stability of samples at higher temperatures than -70 °C have not been assessed.

DOCUMENTATION AND LABELING

Label samples with labels generated by your facility. These should be -80 °C compliant to ensure they remain attached to the samples while frozen. Text should be electronically printed or hand-written in felt-tip permanent marker. Barcodes (1D or 2D) are acceptable and preferred.

Myriad RBM's standard shipping form should be completed prior to shipping and included in the package, as well as a sample manifest, to aid in consistent receiving and handling. The human sample submission form (SSF) can be found on our website at MyriadRBM.com/order/how-to-order/.

SAMPLE SHIPPING AND HANDLING

Samples are to be shipped overnight/international priority, preferably Monday-Wednesday shipping for arrival Tuesday-Thursday. The sample tubes (when possible) should be placed in cryoboxes, rather than bags, to minimize damage to the samples. Shipments should be prepared according to biohazard regulations and shipped frozen, in a Styrofoam container with sufficient dry ice to maintain temperature (less than -80 °C) for at least 48 hours. Use Styrofoam-insulated corrugated fiberboard outer packaging containers. Samples may be rejected for analysis if the sample container is broken or leaking or the samples show evidence of thawing.

Please remember to include the completed copy of Myriad RBM's Sample Submission Form (SSF) along with an itemized list of contents and any other documentation that is specifically required by the country of origin for the samples being shipped.

Samples sent for Myriad RBM services, Vectra DA analysis or both are to be shipped to Myriad RBM. If both services are required, two separate aliquots per sample that are clearly designated for the service to be performed (Vectra or Myriad RBM services) and two sample manifests are required. Upon sample reconciliation, aliquots requiring Vectra DA analysis will be shipped by Myriad RBM to our sister company's (Crescendo Bioscience) CLIA lab in South San Francisco for completion of the testing.

Note: "Universal Precautions" for bloodborne pathogens should be employed when handling all samples.

SHIPPING SPECIMENS

Myriad RBM Services & Vectra DA Testing

Please forward tracking numbers and send inquiries to receiving@myriadrbm.com.

Collected and packaged specimens should be sent to:

Kalyn Sowell
Myriad RBM, Inc.
3300 Duval Road
Austin, TX 78759
(512) 275-2644

Vectra, Crescendo Bioscience, and the associated logos are trademarks or registered trademarks of Crescendo Bioscience, Inc in the United States and other jurisdictions.

myriadrbm.com/VectraDA

Vectra DA is validated for use in adults diagnosed with RA. Test results are intended to aid in the assessment of disease activity in RA patients when used in conjunction with standard clinical assessment. This test is not intended or validated to diagnose RA.

Vectra, Crescendo Bioscience, and the associated logos are trademarks or registered trademarks of Crescendo Bioscience, Inc in the United States and other jurisdictions. © Crescendo Bioscience, Inc. All rights reserved.



341 Oyster Point Boulevard
South San Francisco, CA 94080
Toll-free 1-877-RHEUMDX (1-877-743-8639)
www.crescendobio.com
customerservice@crescendobio.com

REV 08.16