

Procedure	Requests for Repeats of Approved Results
------------------	---

Prepared by	Date Adopted	Supersedes Procedure #
Steven Whitford	July 1, 2015	

Review Date	Revision Date	Signature
	July 2015	Gordon Williams

Distributed to	# of Copies	Distributed to	# of Copies

I. PURPOSE

To describe the procedure for handling investigator requests to repeat samples with approved results. at the Brigham Research Assay Core.

II. RESULT APPROVAL

All results at the BRAC are subjected to a rigorous process to ensure their accuracy. All assays are tested for accuracy, and each technician is tested for competency for each method on a semi-annual basis. Each assay run has multiple levels of known samples (controls) tested at the beginning and end of each run. Controls are also run in the middle of an assay in larger runs. All samples in manual assays are run in duplicate to confirm the result.

When the testing is complete, each assay is evaluated by the lab manager or lab director, taking into account several factors in addition to the control result.

III. REQUESTING REPEATS

If investigators wish to request a sample repeated, they are to contact: Bharti Thakkar for BRAC approval. It is preferred that the investigator provide a fresh aliquot for testing.

All repeat requests should be made as soon as possible, as samples are often returned to the investigator or discarded after completion (See SOP 540 – Sample Storage Policy)

IV. TIMEFRAME FOR PERFORMING REPEATS

The actual running of the samples will depend on the current workload, and availability of supplies. At minimum, there is often a delay of a week for new supplies to be ordered and shipped. At the Lab Manager's discretion, the testing may additionally be delayed in order receive enough other samples to be cost effective for the assay.

V. CALCULATION OF COSTS

In most cases the result is similar to the original value. When this occurs, the study will be charged for the cost of the extra test.

Rarely, the result does differ from the original value. If the %CV between the new and result is >20%, it is considered an assay error, and the study will not be charged for the new result. At the Lab manager's discretion, the sample may be repeated again to confirm, but the study will not be charged for this confirmation.

VIII. REFERENCES

1. Brigham and women's Hospital Clinical Laboratory Manual 2009
2. Tietz, Norbert W., Clinical Guide to Laboratory Test, 1990, W.B. Saunders Company, Philadelphia, PA.
3. National Committee for Clinical Laboratory Standards, NCCLS Procedure Manual Template, 1993, Villanova, PA