

Nerurkar, Mukul (NIH/NHGRI) [C]

To: Powell, Cynthia M.
Subject: RE: G150258/R003 Review Complete

From: Powell, Cynthia M. <powellcm@med.unc.edu>
Sent: Monday, January 7, 2019 1:56 PM
To: Milko, Laura V. <laura_milko@med.unc.edu>; Berg, Jonathan Sanford <jonathan_berg@med.unc.edu>; Souris, Katherine Janine <kjsouris@unc.edu>; Roche, Myra <myra_roche@med.unc.edu>; Powell, Bradford C <bcpowell@email.unc.edu>; Roman, Tamara <troman@email.unc.edu>; Butterfield, Rita M <rbutterfield@unc.edu>; Weck, Karen <Karen.Weck@unchealth.unc.edu>; Lewis, Megan <melewis@rti.org>; Christine Rini <Christine.Rini@hackensackMeridian.org>
Subject: FW: G150258/R003 Review Complete

FYI – no comments from FDA just notification that the review was finished. I heard from Paula last week with a question about whether we were confirming positive sequencing results in a CLIA lab.
Thank you all for your help.

Cindy

From: Paula Velasco Caposino <paula.caposino@fda.hhs.gov>
Sent: Monday, January 7, 2019 12:56 PM
To: Powell, Cynthia M. <powellcm@med.unc.edu>
Cc: Paula Velasco Caposino <paula.caposino@fda.hhs.gov>
Subject: G150258/R003 Review Complete

January 7, 2019

FDA has completed its review. Please refer to the attached document(s).

If you have any questions, please contact the lead reviewer assigned to your submission, Paula Velasco Caposino (copied above).

*** This is a system-generated email notification ***