TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	4/8/2016
Department:	Technical Mgmt & QA	**Due Date:**	4/20/2016
		Implementation:	**4/20/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Procedure for Revised Report Tracking/Reporting Dashboard Metrics GEC/ SGAH /WAH QDNQA701 v2.2
Description of change(s):
Section 3: change SOP review to periodic Section 7: change RQI SOP to Hospital version This revised SOP will be implemented on April 20, 2016

Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training (version 2.2)

Title	**Procedure for Revised Report Tracking/Reporting Dashboard Metrics**
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Owner	Lilli Visnapuu, M.D.

Corporate Approval	
National Quality Assurance	Lilli Visnapuu, M.D., Director, National Quality Assurance
Signature	Lilli Visnapuu, M.D. Date: 4/1/04
Corporate Medical	Joyce G. Schwartz, M.D., Vice President & Chief Laboratory Officer
Signature	Joyce G. Schwartz, M.D. Date: 4/1/04
Corporate Issue Date	4/1/04
Corporate Effective Date	4/1/04

Local Approval	**Site:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name and Title	**Signature**	**Date**

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1. PURPOSE

This document sets forth:

- A standard system by which the number and root causes of Revised Reports (see "Definitions") can be comprehensively tracked at the Business Unit (BU) level.
- The procedure that BU staff is to follow to report Revised Report metrics to the corporate Dashboard (see "Definitions").

2. SCOPE

This procedure applies to all Quest Diagnostics BUs that report data to the corporate Dashboard, including Nichols Institute, Chantilly and Nichols Institute, San Juan Capistrano.

3. RESPONSIBILITY

- The BU's **Revised Report Gatekeepers** (see "Definitions") in Main Laboratories, Rapid Response Laboratories (RRLs) and Anatomic Pathology (AP) referral laboratories are responsible for reporting the issuance of Revised Reports and associated information to the Main Laboratory's Local Quality Assurance (QA) Manager.
- The **Local QA Manager** is responsible for 1) collecting information from the BU's Gatekeepers, 2) submitting data to the Dashboard and 3) preparing monthly quality management reports.
- The **Laboratory Director, Operations Director, Branch Operations Manager** (if applicable) and **Local QA Manager** are responsible for reviewing the monthly quality management reports and initiating corrective action as needed.
- **Technical Supervisors** are responsible for implementing this procedure in the departments for which they are responsible.

- The **Laboratory Director** is responsible for the initial approval of this SOP and any subsequent revisions.
- The **Laboratory Director or Designee** is responsible for the periodic review of this SOP.

4. DEFINITIONS

- **Dashboard:** A corporate operations and quality management report system maintained on the Quest Diagnostics intranet
- **Reportable Quality Issue (RQI):** A quality issue that is of sufficient priority to require the notification of National Quality Assurance (NQA)(see "Related Documents"); **Corporate RQIs** typically involve multiple laboratories, with the corrective action being determined/managed by NQA under the direction of the Legal Department.
- **Revised Report:** A patient report reissued to the client where there has been a clinically significant change in the previously reported result/interpretation (see Appendix A—"Detailed Definition of Revised Report")
- **Revised Report Gatekeeper:** Any individual who issues Revised Reports

5. PROCEDURE

A. Gatekeeper's Procedure

1) The Gatekeeper logs every Revised Report he/she issues on a "Gatekeeper Revised Report Log" (Microsoft Excel spreadsheet--see Appendix B), whether it is a Revised Report issued in singlet or a set of Revised Reports associated with one issue.
2) Follow the steps below to enter data into the "Gatekeeper Revised Report Log":

Step	Data	Action
1	"Date"	• For single Revised Reports, enter the date the Revised Report was issued • For sets of Revised Reports, enter the date the first Revised Report in the set was issued
2	"#Rpts"	Enter "1" for a single Revised Report or the number of Revised Reports comprising a set
3	"Site"	Enter "Core Lab" if the Revised Report originated from the Main Laboratory or the section name of the originating RRL.

Step	Data	Action	
4	"Category"	Determine the Revised Report category as follows:	
		If…	**Then…**
		BU staff made an error	Enter "BU"
		The client made an error	Enter "Client"
		The referral laboratory made an error	Enter "Ref Lab"
		Revised Reports were issued as part of the corrective action for a supplier related corporate RQI (see "Definitions")	Enter "SupCorpRQI"
		Revised Reports were issued as part of the corrective action for an Information Technology (IT) related corporate RQI	Enter "ITCorpRQI"
		There was no error	Enter "No error"
		Categorization does not fall under any of the above	Enter "Other"
5	"Dept, Ref Lab or Client (if applicable)"	Enter data as follows:	
		If…	**Then…**
		BU staff made an error	Enter the name of the involved department and, if applicable, the name of the involved instrument (e.g., AutoChem/AU5000)
		The client made an error	Enter the client's name or number
		The referral laboratory made an error	Enter the referral laboratory's name
6	"Code"	Enter the applicable classification code (see Appendix C—"List of Revised Report Categories and Classification Codes")	
7	"Test(s)/ Analyte(s)"	Enter the name of the test(s)/analyte(s)	
8	"Accession#(s)"	Enter the accession number(s) of the Revised Report(s)	

3) **By the third working day of each month**, email the completed "Gatekeeper Revised Report Log" for the previous month to the Local QA Manager.

4) Note 1: Use of the specific "Gatekeeper Revised Report Log" spreadsheet included in this SOP, while strongly recommended, is not required. An alternate document/file can be used to record and transmit the above information to the Local QA Manager.
5) Note 2: Recording the Revised Report category, while strongly recommended, is not required as long as the local system allows for 1) easy segregation of BU (the only category reported to the Dashboard) from other categories of Revised Reports and 2) the preparation of monthly quality management reports that allow for the a) effective analysis of root cause and b) prompt initiation of corrective action, as needed, for all categories of Revised Reports.
6) Note 3: BUs may modify the classification codes listed in Appendix C or use a different list as long as these codes provide the basis for the BU's meeting the above outlined objectives.

B. Local QA Manager's Procedure for Submitting Dashboard Data

1) By the third working day of each month, the Local QA Manager will have received from all Gatekeepers their "Gatekeeper Revised Report Log" spreadsheets completed for the previous month.
2) Merge all Gatekeepers' spreadsheets into one "Revised Report Master Spreadsheet" (see Appendix D).
3) Follow the steps below:

Step	Action
1	Document the source of the data by entering the Gatekeeper's name/initials under "Source".
2	Sort on "Category" to isolate Revised Reports where the category is BU
3	Sort on "Date" to isolate data for the previous month
4	For the previous month's data, determine "Total #Revised Reports Issued Due to BU Error" by taking a sum of the data under "#Rpts"
5	By the fifth working day of the month, submit "Total #Revised Reports Issued Due to BU Error" for the previous month to the individual in the BU responsible for Dashboard data entry

4) Note 1: Only Revised Reports due to BU error (classification codes 1 though the 30's, per the system outlined in Appendix C) are to be reported to the Dashboard. ***Revised Reports due to Client error (40's classification codes), Referral Laboratory error (50's), Supplier Corporate RQIs (60's), Information Technology Corporate RQIs (70's), no error (80's) or other causes (90's) are NOT to be reported to the Dashboard***.
5) Note 2: While the Local QA Manager is required to maintain a spreadsheet/file housing all of the information shown on the specific "Revised Report Master Spreadsheet" included in this SOP, use of the specific "Revised Report Master Spreadsheet" Microsoft Excel file is not required (e.g., the Local QA Manager may opt to use an alternative software program). Columns/fields can be added to track additional information per local preference.

C. Local QA Manager's Procedure for Preparing Monthly Reports

1) By the 15th day of each month, access the Dashboard to print quality management reports for the previous month that display Total #Revised Reports Due to BU Error Issued/Total #Accessions Logged (in ppm).
2) In addition, use the data in the "Revised Report Master Spreadsheet" to prepare quality management reports displaying data sorted by "Site," "Category," "Dept, Ref Lab or Client," "Code" and "Test(s)/Analyte(s)." Such root cause analysis will guide corrective action taken, as needed, to reduce the number of Revised Reports.

D. Procedure for Reviewing Monthly Quality Management Reports

1) The Laboratory Director, Operations Director, Branch Operations Manager (if applicable) and Local QA Manager must meet/conference no later than the end of each month to 1) review the quality management reports for the previous month and 2) initiate corrective action to reduce the number of Revised Reports, as needed.
2) Note: If the Laboratory Director, Operations Director, Branch Operations Manager (if applicable) and Local QA Manager are already meeting/conferencing for the same or other purpose within the required timeframe, review of the monthly quality management reports described in this SOP can be incorporated into the already existing forum.

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6. RECORDS MAINTENANCE

Records are maintained according to the requirements for "Laboratory Operations Management Reports" available on the Quest Diagnostics intranet under "Units & Functions," "Legal & Compliance," "Policies & Procedures," "Records Management Program," "Retention Schedule by Function," "Laboratory Operations."

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7. RELATED DOCUMENTS

- Quest Diagnostics corporate SOP *Hospital Notification Process for Reportable Quality Issues*, available on the Quest Diagnostics intranet under "Units & Functions," "Medical Quality," "National Quality Assurance," "Reportable Quality Issues"
- Quest Diagnostics corporate SOP *Pathologist Assessment by Second Review*, available on the Quest Diagnostics intranet under "Units & Functions," "Anatomic Pathology," "Standards," "Standard Operating Policies for AP"

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8. REVISION HISTORY

Version	Date	Revision Purpose	Name	Approved by
1.0	3/26/01	N/A – Corporate procedure issued	N/A	
2.0	4/1/04	N/A – Corporate procedure re-issued	N/A	
2.0	2/5/09	Minor updates to header and footer Supersedes SOP QA004.001	L. Barrett	C. Bowman
A	3/28/16	Section 3: change SOP review to periodic Section 7: change RQI SOP to Hospital version Section 8: add approver column Footer: New local version numbering adopted per corporate policy change	L. Barrett	C. Bowman

9. PROCEDURE RETIREMENT

Version	Date	Reason for retirement/superseded by	Name

10. APPENDICES

Appendix	File Name	Title
A	N/A – at end of this file	Detailed Definition of Revised Report
B	RevisedRptTrackProcedure 04-0401_AppB_Gatekeeper.xls	Gatekeeper Revised Report Log (See attachment tab of InfoCard)
C	N/A – at end of this file	List of Revised Report Categories and Classification Codes
D	RevisedRptTrackProcedure 04-0401_AppD _Master.xls	Revised Report Master Spreadsheet (See attachment tab of InfoCard)

APPENDIX A

Detailed Definition of Revised Report

A **Revised Report** is a patient report reissued to the client where there has been a clinically significant change in the previously reported result or result interpretation category
(the term "result interpretation category" refers to, for example, "normal" vs. "abnormal")

- **Change in result or result interpretation category**
  - Invalidation (i.e., TNP—"Test Not Performed") of an *incorrect* previously reported result*
  - For quantitative or semi-quantitative results, a statistically significant change that:
    - Causes the result interpretation category to change (e.g., "normal" changes to "abnormal" or "abnormal" changes to "normal")
    - Is otherwise deemed clinically significant by the Medical Director or designee
  - Qualitative Results
    - Clinical Pathology
      - For coded qualitative results, any change in a result code
      - For free-text qualitative results, a change deemed clinically significant by the Medical Director or designee
    - Anatomic Pathology-- for coded or free-text qualitative results/comments, any change that in the opinion of the Medical Director or designee would significantly impact current patient care* *
- **Change in reference range that causes the result interpretation category to change** (e.g., "normal" changes to "abnormal" or "abnormal" changes to "normal")
- **Change in demographic/clinical information that results in the application of a different reference range that, in turn, causes the result interpretation category to change** (e.g., "normal" changes to "abnormal" or "abnormal" changes to "normal")

* Reissued reports where 1) a correct result is TNPd or 2) a TNP is changed to a correct result are patient care neutral (assuming there is timely notification of clients in the case of a delay in result reporting). As such, these types of reissued reports are NOT to be counted as Revised Reports.

** In the Quest Diagnostics corporate SOP *Pathologist Assessment by Second Review*, an example of a change in a tissue result that would significantly impact current patient care is "a false negative unqualified benign diagnosis such as Compound Nevus that is changed to Malignant Melanoma." According to Corporate Anatomic Pathology (AP), changes in Pap results that would significantly impact current patient care include Negative for Intraepithelial Lesion (NIL) to an abnormal interpretation or NIL to Unsatisfactory specimen adequacy (per the interpretation of Corporate AP, reissued Pap reports with changes in the absence/presence of infectious agents or absence/presence of endocervical cells, obscuring blood or obscuring inflammation do not constitute "Revised Reports" according to the above definition).

APPENDIX C

List of Revised Report Categories and Classification Codes

Category	Code	Description
BU	1	BU error not otherwise specified
	2	Specimen evaluation/acceptance error
	3	Pre-analytic data entry error
	4	Pre-analytic specimen handling error
	5	Testing error-- instrument
	6	Testing error-- employee
	7	Post-analytic data release/entry error
	8	Local Information Technology staff error
BU	30	AP only: not otherwise specified
	31	AP only: review of Pap specimen adequacy*
	32	AP only: QA review of previous diagnosis or interpretation
Client	40	Client error not otherwise specified
	41	Additional or changed patient demographic information provided by client
	42	Additional or changed clinical/diagnostic information provided by client
Referral Lab	50	Referral lab error not otherwise specified
	51	Referral lab error: Nichols Institute
	52	Referral lab error: other Quest Diagnostics regional laboratory
	53	Referral lab error: contracted Anatomic Pathology laboratory
Supplier RQI	60	Supplier related Corporate RQI
Corp IT RQI	70	IT related Corporate RQI
No Error	80	No error
Other	90	Other error

*Corporate Anatomic Pathology recommendation is 1) NIL to Unsat or 2) Unsat to Abnormal only