



**Medical Countermeasure Systems  
Joint Project Management Office  
1564 Freedman Drive  
Fort Detrick, Maryland 21702-5041**



**Reply To  
Attention Of:**

SFAE-CBD-MCS-DX

12 Jan 16

**MEMORANDUM FOR RECORD:** All designated laboratories using the Ebola Zaire (Target 1) Real-time RT-PCR Assay Under the Emergency Use Authorization (EUA)

**SUBJECT:** Emergency Use Authorization (EUA) Updated Reporting Requirements

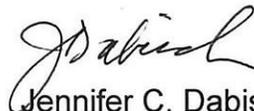
1. In order to maintain compliance with the conditions described in the EUA, the Joint Program Management Office for Medical Countermeasure Systems (JPMO MCS), through the US Army Medical Materiel Development Activity (USAMMDA), is required to report statistics to the US Food and Drug Administration (FDA) on use and performance of the Ebola Zaire (Target 1) real-time RT-PCR (TaqMan) assay (EZ1 assay) on authorized instruments. These instruments are the DOD Joint Biological Agent Identification and Diagnostic System (JBAIDS), the Applied Biosystems Inc. 7500 Fast Dx (ABI 7500 Fast Dx) and the Roche LightCycler.
2. Based on current and forecasted usage, JPMO MCS will now require reporting quarterly vs. monthly. The first report deadline for the time period of 1 January through 31 March will be April 7, 2016. Provide a quarterly report using the EUA Data Reporting Worksheet (Reference 1). Reference 2 describes how to use the EUA data reporting worksheet.
3. Required data includes:
  - Number of patient specimens tested
  - Number of valid test runs and number of invalid test runs (e.g. controls invalid)
  - Number of retests performed and reason for retest
  - Number of specimens tested positive for EBOV
  - Number of tests by specimen (invalid results and suspected false negative/false positive results should include information on specimen type tested)
  - Raw data files (or screen capture images) for all test runs
  - Patient outcomes
  - Suspected adverse events (death or serious injury resulting from suspected false negative and/or false positives), utilizing MedWatch Form FDA 3500A, <http://www.fda.gov/medwatch/getforms.htm>

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SUBJECT: EMERGENCY USE AUTHORIZATION UPDATED REPORTING REQUIREMENTS

- Descriptive notes
  - Quarterly inventory update (amount of kits/tests remaining)
4. All information reported must be stripped of individually identifying patient information in accordance with the Health Insurance Portability and Accountability Act (HIPAA). When setting up test runs and sending data files, the use of lab accessions numbers for authorized instruments may be sufficient to accomplish this.
  5. Reports are due to the JPMO MCS quarterly, no later than the seventh day of the following month. As March is the last month of the initial quarter, the first report will be due by April 7, 2016 and quarterly thereafter, i.e. July, October, etc. Reports and questions can be submitted to the following email address: [usarmy.detrick.imcom.mbx.ebola-eua@mail.mil](mailto:usarmy.detrick.imcom.mbx.ebola-eua@mail.mil)
  6. The EZ1 diagnostic kits can be requested through the MCS Dx Program office; please send requests directly to: [usarmy.detrick.imcom.mbx.ebola-eua@mail.mil](mailto:usarmy.detrick.imcom.mbx.ebola-eua@mail.mil) and [matthew.j.becker37.ctr@mail.mil](mailto:matthew.j.becker37.ctr@mail.mil)
  7. EUA documents can be found on the following websites: FDA:  
<http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm>  
  
USAMMDA Division of Regulated Activities and Compliance (DRAC) website:  
[http://mrmc.amedd.army.mil/sc/ebola\\_eua](http://mrmc.amedd.army.mil/sc/ebola_eua)
  8. Thank you very much for your attention and support of this effort. Continuance of the EUA depends on our ability to maintain compliance with all conditions set out by the FDA for use of the kit and we appreciate your help in doing so.
  9. The Point of Contact (POC) for this memorandum is Jason Opdyke, [jason.a.opdyke.civ@mail.mil](mailto:jason.a.opdyke.civ@mail.mil), (301) 619-2881.

(signed)



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#### References

Reference 1: Ebola EUA Data Reporting Spreadsheet: [http://mrmc.amedd.army.mil/sc/ebola\\_eua](http://mrmc.amedd.army.mil/sc/ebola_eua)

Reference 2: Ebola EUA Data Reporting Spreadsheet Instructions:

[http://mrmc.amedd.army.mil/sc/ebola\\_eua](http://mrmc.amedd.army.mil/sc/ebola_eua)