QUIDEL | AmpliVue®

Anytime, Anywhere Molecular Assays

Technical Bulletin

AmpliVue Assay External Quality Control

Quidel Corporation has carefully investigated the frequency of External Quality Control with the AmpliVue assays as mandated by the Clinical Laboratory Improvement Act (CLIA). We have reviewed all the currently available documents and performed an assessment of the AmpliVue assays.

Based on the Memorandum of the Office of Clinical Standards and Quality/Survey Certification Group there are two mechanisms for meeting the federal guidelines (on file at Quidel Technical Support):

(1) The default mechanism is to follow 42 CFR 493.1256(d)(3) – which states that two levels of external quality control per day of patient testing will be performed. All manufacturer's instructions must be followed, per 42 CFR 493.1256(d)(2).

(2) A new program (Individualized Quality Control Plan (IQCP)) has been announced. The Centers for Medicare & Medicaid Services (CMS) is incorporating into the Interpretive Guidelines (IG), based on 42 CFR 493.1250, key concepts and graphics from Clinical and Laboratory Standards Institute (CLSI) Evaluation Protocol-23 (EP-23), Laboratory Quality Control Based on Risk Management, as alternative Clinical Laboratory Improvement Amendment (CLIA) Quality Control (QC) policy.

Note: The current CLIA Equivalent Quality Control (EQC) will be phased out and will be replaced with IQCP. At the end of the education and transition period, EQC will no longer be an acceptable QC option. After the end date, laboratories found not to be in compliance will be cited accordingly. There will be no grandfathering of existing test systems using EQC.

The key to utilizing the new IQCP program with the AmpliVue assays is a robust assessment of the assay, utilizing the concepts of EP-23. This assessment evaluates each step of the assay using an *Example Failure Mode (Hazard)* model. The method of failure detection utilizes three different control systems (internal, external, and engineered) and the Operator training program. Upon completion of the assessment the laboratory should make a determination on the use and frequency of external controls in the Quality Control program for the given assay.

Quidel has completed its own assessment of the AmpliVue assays using the EP23-A guidelines. Based on our assessment, we have concluded that the use of two levels of external quality control per day of patient testing is not required. We believe that the internal controls built into the AmpliVue assays are sufficient as a means of failure detection. Therefore, we recommend that the use of external controls can be limited to verify the reactivity of each new lot and each new shipment of AmpliVue assays on receipt and before use, as described in the kit Package Insert.

It is recommended that the reactivity of each new lot and each new shipment of the AmpliVue assay be verified on receipt and before use. External control tests should be performed thereafter in accordance with appropriate Federal, State and Local guidelines. The AmpliVue assay should not be used in patient testing if the external controls do not produce the correct results.

Quidel has been in contact with the College of American Pathologist (CAP) regarding the implementation of the IQCP program. CAP indicated the following in a written response:

"The College is still evaluating how we will implement IQCP. It is too soon for us to comment on how it will effect any checklist requirements. We will be releasing the 2014 checklist edition in late spring and I can say that there will not be any changes in the 2014 checklist edition that reflect IQCP."

Until such time as CAP provides clear and specific guidance on the implementation of IQCP, it is Quidel's recommendation that labs consider following the current CAP guidelines in MOL.34220 and MIC.63262. These require validation be performed by daily comparisons of external controls to built-in controls for at least 20 consecutive testing days and then to follow the manufacturer's guidelines or every 30 days whichever is more frequent.

Despite our recommendation, it is ultimately the responsibility of your laboratory to determine the frequency of external control testing with AmpliVue assays as part of your Quality Control program. Questions regarding CLSI EP23-A should be directed to the Clinical and Laboratory Standards Institute (CLSI).

Please contact Quidel Technical Support at 800.874.1517 (in the U.S.), 858.552.1100 (outside the U.S.) or technicalsupport@quidel.com if you have any questions regarding AmpliVue assays, or any Quidel product. Our hours of operation are Monday through Friday, 8:00 a.m. to 5:00 p.m. Eastern Time.

You may also visit our website at **quidel.com** for information on Quidel's line of Molecular Diagnostics, Rapid Diagnostics, Cell Culture and Specialty Diagnostics (Bone Health and Autoimmune & Complement). Other product information available on our website includes: CPT codes, CLSI procedure guides, MSDS, and Package Inserts.

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