

**Title:** Evaluation of the new CK-MB Liquid assay on the ABBOTT ARCHITECT *c*Systems and AEROSET Clinical Chemistry Systems

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**Objective:** The CK-MB Liquid assay was evaluated on ABBOTT ARCHITECT *c*Systems and AEROSET Clinical Chemistry Systems. Scope of the study was to verify the analytical performance and agreement with the desirable specifications based on biological variability as Ricos. (Sc.J.Clin.Lab Invest. 1999;59). **Materials/Instruments:** CK-MB Liquid assay, SENTINEL CH., is an IFCC method based on inhibition of CK-MM with monoclonals and measurement of the remaining enzymatic activity of CK-MB isoform. Abbott's ARCHITECT *c*Systems and AEROSET are random-access clinical chemistry analyzers. ARCHITECT *c*Systems can be integrated with ARCHITECT *i*2000<sub>SR</sub>, an immunoassay module, to form the *ci*8200 or *ci*16200. **Study Design:** Modified CLSI protocols were used. Acceptance criteria were less than 7.5% CV for imprecision and 2.5 U/L bias for accuracy. LOQ was defined as the analyte concentration at which the %CV is less than 20%. Method comparison was evaluated by comparing CK-MB Liquid on ARCHITECT and AEROSET with Roche assay on Hit.912. **Results** (units are U/L): On Architect, assay was linear up to 1115. Total precision was 1.9% at 30 and 1.7% at 79. LOD was 2.3 and LOQ less than 5. Comparison vs Hitachi gave slope 1.04, intercept 0.59, r 0.990, while vs Aéroset gave slope 0.96, intercept -0.24, r 0.997. On Aéroset, assay was linear up to 1316. Total precision was 3.9% at 29 and 1.7% at 79. LOD was 1.5 and LOQ less than 5. Comparison vs Hitachi gave slope 1.05, intercept 1.09, r 0.987. On board calibration stability was 6 weeks. CK-MM did not interfere up to 2000 U/L. Bilirubin unconj. (33 mg/dL), Conj. (44 mg/dL), Hb (50 mg/dL), Triglycerides (600 mg/dL) did not interfere. **Conclusion:** Performance of the new CK-MB Liquid assay meets the Desirable Specifications for CK-MB activity measurement on ARCHITECT *c*Systems and AEROSET Systems. Six-weeks calibration stability and robustness to interferences make this assay very suitable for the routine measurement of this critical analyte.