**Abstract (revised)**

**Objective:** Establishment of performance characteristics of Sentinel CKMB UDR Liquid assay on the Beckman Coulter Synchron® LX20 and on UniCel® DxC 600 Clinical Chemistry Systems.

**Conclusion:** The Sentinel CKMB UDR Liquid assay was evaluated on the Beckman Coulter Synchron® LX20 and on UniCel® DxC 600. The assay was found to meet the acceptance criteria as per the guidelines of the CLSI EP09-A2 and EP17-A guidelines.

**Method Comparison**

**Limit of Quantitation (LoQ)**

<table>
<thead>
<tr>
<th>Target Conc. (U/L)</th>
<th>Limit of Quantitation (CLSI/EP17-A)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.60 U/L (CV &lt; 20%, Bias ≤ 7.8%)</td>
</tr>
</tbody>
</table>

**Linearity**

<table>
<thead>
<tr>
<th>Referenced Conc. (U/L)</th>
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<th>Linearity (Bias ≤ 10%</th>
<th>R²</th>
<th>%CV</th>
</tr>
</thead>
</table>
| 0.5                    | 0.5                    | 0.990                 | 1.1 | -7.3%
| 10                     | 10                     | 0.992                 | 0.6 | 8.1% |

**Interferences**

- Lipemia: No interference up to 1000 mg/dL
- Hemoglobin: No interference up to 100 mg/dL
- Unconjugated Bilirubin: No interference up to 60 mg/dL
- Conjugated Bilirubin: No interference up to 60 mg/dL
- Ascorbic Acid: No interference up to 60 mg/dL
- Pyruvate: No interference up to 3 mg/dL
- Conclusions: The Sentinel CKMB UDR Liquid assay was found to be robust and reliable on both the Synchron® LX20 and UniCel® DxC 600 systems.

**Method Comparison**

**On Board Reagent Stability**

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<td>10</td>
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**Endogenous Interferences**

- Lipemia: No interference up to 1000 mg/dL
- Hemoglobin: No interference up to 100 mg/dL
- Unconjugated Bilirubin: No interference up to 60 mg/dL
- Conjugated Bilirubin: No interference up to 60 mg/dL
- Ascorbic Acid: No interference up to 60 mg/dL
- Pyruvate: No interference up to 3 mg/dL

**Conclusions:** The Sentinel CKMB UDR Liquid assay was found to be robust and reliable on both the Synchron® LX20 and UniCel® DxC 600 systems. The assay was found to meet the acceptance criteria as per the guidelines of the CLSI EP09-A2 and EP17-A guidelines. The assay was found to be robust and reliable on both systems, with no significant interferences observed. The assay was found to be suitable for routine measurement of CKMB in clinical practice.

**Methods comparison:** Performance of Sentinel CK-MB Liquid assay was evaluated on the Beckman Coulter Synchron® LX20 and on UniCel® DxC 600. The assay was found to meet the acceptance criteria as per the guidelines of the CLSI EP09-A2 and EP17-A guidelines.

**Conclusion:** The Sentinel CK-MB Liquid assay was found to be robust and reliable on both the Synchron® LX20 and UniCel® DxC 600 systems. The assay was found to meet the acceptance criteria as per the guidelines of the CLSI EP09-A2 and EP17-A guidelines.

**Method Comparison**

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**Interferences**

- Lipemia: No interference up to 1000 mg/dL
- Hemoglobin: No interference up to 100 mg/dL
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**Conclusions:** The Sentinel CK-MB Liquid assay was found to be robust and reliable on both the Synchron® LX20 and UniCel® DxC 600 systems. The assay was found to meet the acceptance criteria as per the guidelines of the CLSI EP09-A2 and EP17-A guidelines. The assay was found to be robust and reliable on both systems, with no significant interferences observed. The assay was found to be suitable for routine measurement of CKMB in clinical practice.