



**Bio-Rad  
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## 510(k) Summary

### Submitter

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### Contact Person

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### Date of Summary Preparation

May 17, 1996

### Device (Trade & Common Name)

Liquichek Immunoassay Plus Control

### Classification Name

CFR 862.1660: Multi-Analyte Controls, All Kinds (Assayed and Unassayed)

### Devices to Which Substantial Equivalence is Claimed

Tri-Point Liquimmune Control  
Medical Analysis Systems, Inc.  
Camarillo, CA  
K954322

### Statement of Intended Use

Liquichek Immunoassay Plus Control is intended for use as an assayed quality control serum to monitor the precision of a laboratory testing procedures for the analytes listed in this package insert.



Description of the Device

Liquichek Immunoassay Plus Control is prepared from human serum with added constituents of human and non-human origin. The control is provided in liquid form for convenience.

Statement of How Technological Characteristics Compare to Substantial Equivalence Device

A table is provided below comparing the similarities between the Bio-Rad Liquichek Immunoassay Plus Control and the devices to which substantial equivalence is claimed.

	Bio-Rad Liquichek Immunoassay Plus Control	MAS Tri-Point Liquimmune Control
Intended Use	To monitor the precision of a laboratory testing procedures for the analytes listed in the package insert.	A consistent test sample of known concentration for monitoring assay conditions in many immunological determinations.
Form	Liquid	Liquid
Matrix	Human Serum	Human Serum
Customer Storage	1) -10 to -20°C; 2) 30 days at 2-8°C for all analytes except folate and T3Total which are stable for 14 days	1) 90 Days from receipt at 2-8°C
Open Vial Claim	14 Days at 2-8°C for all analytes; except Folate which is stable for 7 Days at 2-8°C	30 Days at 2-8°C