510(k) #: _____ **510(k) Summary**

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Contact Details 21 CFR 807.92(a)(1)

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Device Name 21 CFR 807.92(a)(2)

Device Trade Name: DAT Control, MTS™ DAT Card

Common Name: Quality control kit for blood banking reagents

Classification Name: Kit, Quality Control For Blood Banking Reagents

Regulation Number: 864.9650

Product Code(s): KSF

Legally Marketed Predicate Devices 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name	Product Code
BK1600061	MTS™ Monoclonal Control Card	KSF

Device Description Summary 21 CFR 807.92(a)(4)

The DAT Control is not intended for use alone in testing human blood but is intended for use in parallel with the biologic microtubes contained within the MTS™ DAT Card, to fulfill the device's intended function, to confirm the validity of the associated IgG and complement results for the DAT test.

The DAT Control is contained within two of the six microtubes of the Anti-Human Globulin Anti-IgG (Rabbit)/Anti-C3b,-C3d (Murine Monoclonal)/DAT Control, MTS™ DAT Card.

Please note that in the Instructions for Use for MTS™ DAT Card the DAT Control is referred to as the "control microtube", "control test" or "Control".

The MTS™ DAT Card is designed to be used in the direct antiglobulin test. This direct antiglobulin test allows the differentiation of human red blood cells sensitized in vivo by IgG type immunoglobulins (detected by microtubes 1 & 4) or complement C3b and or C3d fractions (detected by microtubes 2 & 5). The DAT Control (microtubes 3 & 6) contain the same diluent and buffer gel suspension with no antibodies.

A positive reaction in the DAT Control microtube (microtube 3 or 6) indicates that a false positive reaction or spontaneous agglutination may have occurred in the direct antiglobulin test microtube(s) of the MTS™ DAT Card.

A positive reaction in the DAT Control microtube invalidates the associated IgG and complement results for the DAT test.

The MTS™ DAT Card interpreted result is based on the results of both the Anti-IgG and Anti-C3b,-C3d microtube results. A sample is interpreted as DAT positive if either one or both Anti-IgG and Anti-C3 microtubes is positive, and negative if both microtubes display no reaction. If agglutination occurs (positive reaction) in the DAT Control microtube, the test is invalid and no interpretation of the other two microtubes can be made.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The DAT Control is intended for use in parallel with the biologic microtubes contained within the MTS™ DAT Card for the confirmation of the validity of the associated IgG and complement results for each sample tested.

A positive result in the DAT Control microtube indicates that a false positive reaction or spontaneous agglutination may have occurred in the direct antiglobulin test microtube(s) of the Anti-Human Globulin Anti-IgG (Rabbit)/Anti-C3b,-C3d (Murine Monoclonal)/DAT Control, MTS™ DAT Card. A positive DAT Control result would render the results in the other microtubes to be invalid and thus, no interpretation of DAT status can be made.

Comparison to Predicate Devices 21 CFR 807.92(a)(6)

The DAT Control is used as a quality control for direct antiglobulin testing; the predicate is a quality control for blood grouping tests. The predicate and the DAT Control have the same technological characteristics, similar reagent composition and are used with immunohematology gel technique, ID-Micro Testing System™.

Table 2 Comparison to Predicate		
Trade Name	**Predicate MTS™ Monoclonal Card (BK160061)**	**Candidate DAT Control MTS™ DAT Card microtubes 3 & 6**
Classification Name	Quality Control for Blood Banking Reagents	Quality Control for Antihuman Globulin Reagents
Device Class	Class 2	Same
Product Code	KSF	Same
Regulation Number	864.9550	Same
Device Description	The MTS™ Monoclonal Control Card is manufactured using the same diluent formula as used in the MTS™ Monoclonal Blood Grouping Cards with no antibodies.	The MTS™ DAT Card control microtube is manufactured using the same diluent (Anti-Human Globulin Buffer (AHG)) as used in MTS™ DAT Card microtubes 1,2, 4 and 5 with no antibodies.
Indications for Use	A positive reaction in the MTS™ Control microtube indicates a false positive reaction may have occurred in the corresponding blood grouping microtube, thus invalidating the blood grouping tests.	A positive reaction in the MTS™ DAT Card control microtube indicates a false positive reaction may have occurred in the direct antiglobulin microtube(s), thus invalidating the DAT tests.
Principle of the Test	Immunohematology gel technique	Same
Reagent Composition	Contains sodium azide (preservative), sodium chloride, disodium ethylenediamine tetraacetic acid (EDTA), and bovine serum albumin (potentiator) in an imidazole buffer system (pH 7.0-7.4).	Same Reagent Composition with a TRIS buffer system (pH 7.0-7.4).

Both formulations are designed for use in parallel with the biologic microtubes contained within the associated MTS™ Gel Card, to fulfill the device's intended function. A positive reaction in the Control microtube indicates that a false positive reaction or spontaneous agglutination may have occurred in the microtube(s) of the associated biologic test.

Non-Clinical and Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical performance testing included repeatability, interference, anticoagulant and sample stability, in addition to on-analyzer serological timeout restrictions, environmental testing and DAT Control stability testing. Results demonstrate the ability of the DAT Control to function as expected in the MTS™ DAT Card when processed manually on the ORTHO® Workstation and with automated the ORTHO VISION® and VISION® Max Analyzers.

Clinical equivalency testing is presented in this submission to demonstrate the intended function of the DAT Control microtube when used in parallel with the biologic microtubes contained within the MTS™ DAT Card.

The DAT Control performed as expected in the detection of agglutination of two samples, indicating invalid results which were excluded from the clinical equivalency study as per protocol. These samples were found to be contrived samples heavily coated with antibody.

Per the MTS™ DAT Card customer instructions for use, if the DAT Control (microtube 3 or 6) is positive, a valid interpretation of the results obtained cannot be made. The observation of unexpected agglutination in the DAT Control and Anti-IgG microtubes, in this evaluation demonstrated that the DAT Control will meet its intended use to indicate that a false positive reaction may have occurred in the direct antiglobulin test microtube(s).

The proposed device is substantially equivalent to the predicate device relative to technological characteristics, formulation, and manufacturing process. Both formulations are designed for use in parallel with the biologic microtubes contained within the associated MTS™ Gel Card, to fulfill the device's intended function. A positive reaction in the Control microtube indicates that a false positive reaction or spontaneous agglutination may have occurred in the microtube(s) of the associated biologic test.

The successful performance testing demonstrates the safety and efficacy of the DAT Control when used for the defined indications as a component of the Anti-Human Globulin Anti-IgG (Rabbit)/Anti-C3b,-C3d (Murine Monoclonal)/DAT Control, MTS™ DAT Card.