



Completed Work

A Partial Selection of Completed Work by MDC

Regulatory Projects

FDA Clearance for the following projects

- > The first over-the-counter test for detection of Urinary Tract Infection
- > Over-the-counter for a test for the detection of protein in urine
- > Over-the-counter and professional pregnancy tests
- > Over-the-counter approval for an early detection Pregnancy test
- > A variety of professional and over-the-counter Drug of Abuse Assays
- > Automated and manual Urinalysis
- > Fecal Occult Blood Immunology Test
- > Molecular products for:
 - HSV
 - Flu
 - RSV
 - Van R
 - C. Difficile

Received CLIA waiver for

- > Rapid Group A Streptococcus product
- > Rapid, automated urinalysis system
- > Drug of Abuse Assays

Quality System Projects

- > Aided a well established Chemistry Reagent company to resolve quality system issues and clear a long standing warning letter. During the warning letter follow-up FDA inspection, all deficiencies noted in the warning letter were resolved. No 483 was issued.
- > Developed a quality system for a manufacturer of rapid tests. Prior to MDC involvement the company had received an extensive warning letter. Under MDC's direction the warning letter was resolved. Company continues to maintain an effective quality system, and all subsequent FDA inspections resulted in no major deficiencies.

Call Center Projects

- > Call center services for a leading supplier of blood pressure monitors
- > Call center support for key Glucose monitor companies
- > Technical support for an automated Clinical Chemistry System
- > Call Center Support for Cardiac monitoring System

Training programs

- > Automated clinical chemistry system
- > AIC analyzer
- > Hematology products
- > Immunoassay tests

Market Research

Analysis of the following markets

- > Molecular infectious disease market
- > Rapid Cardiac monitoring market
- > Group B Streptococcus market
- > Potential of genomic testing



Our experience ensures your success.

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