

A034 MicroVue™ Ba Fragment EIA (Complement)

(contains: 5159 – 5163, Ba Standards; 5164/5165, Low/High Controls; 5166, Microassay Plate; A9947, Stop Solution; A9957, 20X Wash Buffer; A3670, Complement Specimen Diluent; 5059, TMB Substrate; 5167, Conjugate)

Description: The MicroVue Ba Enzyme Immunoassay Kit measures the amount of the complement fragment Ba, an activation fragment of Factor B of the alternative pathway of complement, in human urine, plasma or serum. Measurement of Ba in human urine, plasma or serum provides evidence of the involvement of the alternative pathway of complement. Activation of the alternative pathway has been associated with several kidney diseases, e.g., chronic glomerulonephritis, lupus nephritis, as well as several skin diseases, e.g., dermatitis herpetiformis and pemphigus vulgaris. Other diseases in which activation of the alternative pathway of complement has been implicated include age-related macular degeneration, fetal loss in at-risk pregnancy, rheumatoid arthritis, and sickle cell anemia.

We, QUIDEL Corporation ensure and declare with sole responsibility, that the above-mentioned products meet the provisions of Council Directive 98/79/EC (IVD directive) as transposed into national regulation.

Wir, QUIDEL Corporation, stellen sicher und erklären mit alleiniger Verantwortung, dass die oben erwähnten Produkte die Bestimmungen der Richtlinie 98/79/EC (IVD-Richtlinie), umgesetzt in nationales Recht, erfüllen.

Nous soussignés, QUIDEL Corporation assurons et déclarons que les produits mentionnés ci-dessus sont en conformité avec la directive européenne 98/79/CE (directive sur les dispositifs médicaux de diagnostic in vitro) en tant que transposée dans la réglementation nationale.

Noi QUIDEL Corporation sono i soli responsabili, assicura che i prodotti suddetti soddisfano le clausole della direttiva del Consiglio 98/79/ec (Direttiva IVD) e recepite nell'ordinamento nazionale.

Nosotros, QUIDEL Corporation aseguramos y declaramos bajo nuestra única responsabilidad, que los productos arriba mencionados cumplen los requisitos de la directiva del Consejo 98/79/EC (directiva IVD) transformado en la normativa nacional.

Nós, QUIDEL Corporation, asseguramos e declaramos sob nossa única responsabilidade, que os produtos acima mencionados cumprem os requisitos da Directiva do Conselho 98/79/EC (Directiva DIV), transpostas para os regulamentos nacionais.

Wij, QUIDEL Corporation, als enige verantwoordelijk, verklaren en verzekeren hierbij dat de bovengenoemde producten voldoen aan de eisen gesteld in de EG Richtlijn 98/79/EC (IVD richtlijn), zoals omgezet in nationale regelgeving.

My, QUIDEL Corporation zapewniamy i deklarujemy na własną odpowiedzialność, że wymienione wyżej produkty spełniają przepisy dyrektywy Rady 98/79 / WE (dyrektywy IVD) transponowane do przepisów krajowych.

Classification: Article 9(1) of EC Council Directive 98/79/EC on *in vitro* diagnostic devices

Conformity assessment route: Annex III (IVDD self-affixed)



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Signed this 26th day of February, 2019

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