

DIAGNOSTICS CATALOG



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SIMPLIFYING DIAGNOSTICS • IMPROVING GLOBAL HEALTH



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About CTK Biotech

Simplifying diagnostics. Improving global health. Located in San Diego, California, an area well known for biotechnology and scientific discovery, CTK Biotech develops and manufactures innovative immunodiagnostic tools and point of care diagnostic test kits for the IVD community worldwide. Our IVD products allow medical professionals to quickly and accurately diagnose disease and meet patient needs. The simplicity and portability of our test kits make them ideally suited for use in a wide range of settings including remote locations and countries with large populations where complicated medical diagnostic systems are not readily available.

CTK Biotech is focused on quality and strives to stay ahead of changing market conditions. With top notch experts at the helm, we identify and adopt new technologies, plan for upcoming trends and achieve commercialization as a result of our advances. CTK invests heavily in research to develop new products in response to market demands and continuously improve our point of care tests. For each step of product development we have established a proficient pathway to convert scientific discoveries and the latest technologies into diagnostic solutions for use in the real world.

We have a unique business model in that we produce our own recombinant antigens and antibodies for later use in the production of our test kits. Our skill in raw material identification, generation and purification gives us an edge over our competitors as we can guarantee excellent control over quality, supply and consistency between lots to ensure that our customers receive the highest quality products at exceptional pricing.

Customer service is an equally important factor to our business. We strive to obtain and retain our loyal customers by exceeding their expectations with unparalleled service and creating sustainable value. From navigating the regulatory environment to regular communication from the time of order to delivery, CTK is known for excellence in quality and service.



RAPID TESTS

OnSite Rapid Tests, CTK's flagship product line, are lateral flow immunochromatographic assays designed for use in a range of settings from well-equipped hospitals to remote emergency stations to aid in the diagnosis of a broad range of diseases. The benefits of point of care rapid tests include a rapid time to result, a simple procedure that can be performed without complicated equipment and a minimal need for training.



ELISA KITS

ELISA tests are highly sensitive assays used to detect the presence of antigens or antibodies in a specimen to aid in the diagnosis of disease. The quality of antigens and antibodies against the target is the most important factor in producing ELISA tests with superior performance. CTK produces the antigens and antibodies utilized in our ELISA kits "in-house" which allows us to have complete control of and confidence in our tests.



EXTERNAL CONTROLS

Simple and effective quality control: *Positivia* Rapid Test Control Kits provide users with external controls to evaluate the integrity of the test, ensure users are performing the test correctly and enable compliance with regulatory requirements. *Positivia* External Controls are produced using recombinant protein engineering technology and are shipped lyophilized as conveniently portable yet comprehensive control systems.



Blood Borne

HIV
HBV
HCV
SYPHILIS

Highly sensitive and accurate screening tests for blood borne pathogens are critical to controlling the spread of these diseases by identifying infected individuals and ensuring safe blood supplies. CTK offers highly sensitive and specific *OnSite* Rapid Tests and ELISA Kits that detect IgG and IgM antibodies to the pathogens of primary concern: HIV-1 (including subtype O) and HIV-2, HBV, HCV and Syphilis. For efficient screening of multiple diseases, a unique test format is offered featuring HIV/Syphilis Ab detection on a single strip as well as for HBsAg/HCV Ab detection.

In addition to Ab screening tests, tests that detect viral antigens are useful for early HIV and HBV diagnosis. It has been suggested that HIV infection is detectable with a p24 antigen test 6 days earlier than an antibody test, and the WHO recommends the use of immunoassays against HBsAg to promote early detection of acute HBV infection. CTK also provides a full line of ELISA kits that detect a full range of markers for blood borne infection screening.

OnSite Rapid Test Kits

Catalog #	Product	Specimen	Description
R0011C	HIV 1/2 Ab Plus Combo Rapid Test	S, P & WB	Double antigen based detection method for increased sensitivity
R0015C	HIV 1+2 Ab Plus Combo Rapid Test	S, P & WB	Utilizes gp120-41 antigen to detect HIV-1+2 Abs
R0018C	HIV Ag/Ab 4th Gen. Rapid Test	S, P & WB	Detects p24 Ag & total Abs to HIV-1+2 including subtype O
R0035C	HIV/Syphilis Ab Combo Rapid Test	S, P & WB	3 line test for HIV-1+2 and Syphilis Ab
R0040C	HBsAg Rapid Test	S, P	Highly sensitive and specific detection of HBsAg
R0040S	HBsAg Rapid Test (strip)	S, P	Highly sensitive and specific detection of HBsAg
R0042C	HBsAg Combo Rapid Test	S, P & WB	Analytic detection level as low as 0.5 ng/mL
R0028C	HBsAg/HCV Ab Rapid Test	S, P & WB	3 line test for HBsAg and HCV Ab
R0023C	HCV Ab Plus Rapid Test	S, P	Utilizes double antigen method to detect low level Abs
R0023S	HCV Ab Plus Rapid Test (strip)	S, P	Utilizes double antigen method to detect low level Abs
R0024C	HCV Ab Plus Combo Rapid Test	S, P & WB	100% agreement with BBI Worldwide Performance Panel
R0030C	Syphilis Ab Rapid Test CE	S, P	Treponemal test for direct detection of Syphilis Ab
R0030S	Syphilis Ab Rapid Test (strip) CE	S, P	Treponemal test for direct detection of Syphilis Ab
R0031C	Syphilis Ab Combo Rapid Test CE	S, P & WB	Highly sensitive Ab detection in all stages of disease

Positivia External Control Kits

Catalog #	Product
C0018	HIV-1 P24 Ag Rapid Test Control Kit



ELISA Kits
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Catalog #	Product
E0410	HIV 1+2 Ab ELISA Kit
E0420	HIV 1+2 Ag-Ab ELISA Kit
E0710	HBsAg ELISA Kit
E0711	HBsAb ELISA Kit
E0720	HBeAg ELISA Kit
E0721	HBeAb ELISA Kit
E0810	HBcAb ELISA Kit
E0811	HBc IgM ELISA Kit
E0510	HCV IgG ELISA Kit
E0511	HCV Ab ELISA Kit
E0610	Syphilis Ab ELISA Kit CE





Tropical/Parasitic

DENGUE
MALARIA
LEPTOSPIRA
CHAGAS

LEISHMANIA
FILARIASIS
CHIKUNGUNYA

A number of infectious diseases prevalent in areas with hot, humid climates cause similar symptoms including fever, aches and chills, making them hard for doctors to accurately diagnose at an early stage. Serologic assays for the detection of antigens and antibodies are common methods for the diagnosis of infections with specific infectious agents. CTK specializes in tropical and parasitic diseases and offers a broad range of tests that can be used in combination to guide the management of severe, treatable infections requiring specific therapy.

CTK utilizes a chimeric dengue virus exclusively licensed from the US CDC to achieve highly sensitive and specific detection of both IgG and IgM to all four serotypes of dengue virus. In addition to antibody-detection tests, this line of *OnSite* Rapid Tests includes antigen-detection tests for both dengue and malaria. All *OnSite* Malaria Ag Rapid Tests have been evaluated as part of the WHO Malaria RDT Product Testing Program and meet the acceptability requirements. Uniquely, CTK offers a duo test for dengue and chikungunya viruses as dual infections have been reported.

OnSite Rapid Test Kits

Catalog #	Product	Specimen	Description
R0061C	Dengue IgG/IgM Combo Rapid Test CE	S, P & WB	Utilizes chimeric virus exclusively licensed from US CDC
R0062C	Duo Dengue Ag-IgG/IgM Rapid Test CE	S, P & WB	Two panel test for the detection of dengue Ag and Abs
R0063C	Dengue Ag Rapid Test CE	S, P & WB	Detects dengue Ag from all four serotypes
R0069C	Duo Dengue IgG/IgM-CHIK IgM Rapid Test CE	S, P & WB	Two panel test for dengue and chikungunya Abs
R0111C	Malaria Pf/Pv Ab Combo Rapid Test CE	S, P & WB	Differentiates IgG & IgM to help identify 1° and 2° infections
R0112C	Malaria Pf/Pv Ag Rapid Test CE	WB	Utilizes specific Abs to Pf-HRP II and Pv-LDH, WHO accepted
R0113C	Malaria Pf/Pan Ag Rapid Test CE	WB	Requires only 5 µL specimen volume, WHO accepted
R0101C	Leptospira IgG/IgM Combo Rapid Test CE	S, P & WB	Simple method for serological detection of <i>L. interrogans</i> Abs
R0171C	Chagas Ab Combo Rapid Test CE	S, P & WB	High sensitivity, specificity due to <i>T. cruzi</i> specific antigen used
R0121C	Leishmania IgG/IgM Combo Rapid Test CE	S, P & WB	Utilizes recombinant rK39 antigen to differentiate IgG and IgM
R0122S	Leishmania Ab Rapid Test (strip) CE	S, P	Utilizes recombinant rK39 antigen to detect Abs to <i>L. donovani</i>
R0151C	Filariasis IgG/IgM Combo Rapid Test CE	S, P & WB	Use of conserved Ags allows 'pan-filaria' tests to be applicable
R0066C	Chikungunya IgM Combo Rapid Test CE	S, P & WB	Utilizes recombinant Ag derived from the CHIK structure protein



Positivia External Control Kits

Catalog #	Product
C0063	Dengue Ag Rapid Test Control Kit
C0010	Malaria Ag Rapid Test Control Kit

ELISA Kits

Catalog #	Product
E0310	Dengue IgM ELISA Kit coming soon
E0311	Dengue IgG ELISA Kit coming soon
E0312	Dengue Ag ELISA Kit coming soon
E0110	Malaria Ab ELISA Kit coming soon
E0170	Chagas IgG ELISA Kit CE
E0121	Leishmania Ab ELISA Kit CE
E0315	CHIK IgM ELISA Kit CE





Hepatitis

HAV
HEV
HBV
HCV

Viral hepatitis is most commonly caused by the hepatitis A, B and C viruses, but it can also be caused by infection with hepatitis E virus. The severity of disease varies depending on the causative virus; the first step in diagnosing hepatitis infections is to screen for the type of virus and when it was contracted using highly sensitive immunoassays against virus specific antibodies.

Hepatitis B and C can lead to chronic liver disease and severe damage including cirrhosis and liver cancer. Screening tests are particularly important as many individuals remain undiagnosed until years or decades after initial exposure leading to unrecoverable chronic liver damage and spread of infection. Early and effective detection of hepatitis B or C infections is critical for initiating early treatment which may yield a better prognosis. The presence or

absence of additional antibodies and antigens serve as additional indicators to distinguish between acute and chronic infections enabling medical treatment to be directed accordingly to inhibit disease progression.

Although the clinical presentation in HAV and HEV infections is similar, HAV is usually self-limiting while HEV is more severe resulting in a 1-2% death rate and is often associated with fulminant hepatic failure and subsequent high mortality rates in pregnant women. Thus, distinguishing the etiological agent is of high importance. IgM is a well-established marker of recent infection with antibody responses peaking at about one month after initial infection, and CTK offers both *OnSite* Rapid Tests and ELISA Kits for its detection and differentiation from HAV.

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OnSite Rapid Test Kits

Catalog #	Product	Specimen	Description
R0090C R0092C	HAV IgM Rapid Test CE HAV IgG/IgM Rapid Test coming soon	S, P	Qualitatively detects IgM anti-hepatitis A virus
R0095C R0096C	HEV IgM Rapid Test CE HEV IgG/IgM Rapid Test coming soon	S, P	Qualitatively detects IgM anti-hepatitis E virus
R0040C	HBsAg Rapid Test	S, P	Highly sensitive and specific detection of HBsAg
R0040S	HBsAg Rapid Test (strip)	S, P	Highly sensitive and specific detection of HBsAg
R0042C	HBsAg Combo Rapid Test	S, P & WB	Analytic detection level as low as 0.5 ng/mL
R0049C	HBV-5 Rapid Test	S, P	5-panel test for HBV markers to help determine infection status
R0028C	HBsAg/HCV Ab Rapid Test	S, P & WB	3 line test for HBsAg and HCV Ab
R0023C	HCV Ab Plus Rapid Test	S, P	Utilizes double antigen method to detect low level Abs
R0023S	HCV Ab Plus Rapid Test (strip)	S, P	Utilizes double antigen method to detect low level Abs
R0024C	HCV Ab Plus Combo Rapid Test	S, P & WB	100% agreement with BBI Worldwide Performance Panel



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Catalog #	Product
E0100	HAV IgM ELISA Kit CE
E0105	HEV IgM ELISA Kit CE
E0710	HBsAg ELISA Kit
E0711	HBsAb ELISA Kit
E0720	HBeAg ELISA Kit
E0721	HBeAb ELISA Kit
E0810	HBcAb ELISA Kit
E0811	HBc IgM ELISA Kit
E0510	HCV IgG ELISA Kit
E0511	HCV Ab ELISA Kit





Respiratory

TUBERCULOSIS STREP A INFLUENZA

Respiratory tract infections range in severity from relatively mild infections, such as the common cold to potentially life-threatening infections. The clinical presentation of patients with respiratory tract infections, particularly early in the disease course, often does not yield a specific diagnosis because the signs and symptoms are non-specific. While a specific diagnosis is not always necessary, reliable and timely diagnoses can be important in managing patient care, preventing the secondary spread of infection and implementing appropriate antibiotic or antiviral treatment.

CTK's respiratory products include *OnSite* Rapid Tests to diagnose acute respiratory infections, both viral and bacterial. With the trend of more global outbreaks of influenza, the laboratory rapid test has become a much needed tool for screening patients with suspected infections. The recent emergence of drug-resistant strains of *Mycobacterium tuberculosis* has rekindled interest in serological differentiation of fresh, previous and chronic *M.TB* infections. The direct detection of group A streptococcal antigen is possible in a matter of minutes, facilitating prompt and effective treatment to prevent progression into more severe disease.

OnSite Rapid Test Kits

Catalog #	Product	Specimen	Description
R0053C	TB IgG/IgM Combo Rapid Test CE	S, P & WB	Allows detection of IgM in patients vaccinated with BCG
R0184S	Strep A Rapid Test (strip) CE	Swab	Detects Strep A antigens in throat swab specimens
R0187S	Influenza A/B Rapid Test (strip) CE	Swab	3 line test to differentiate Influenza A & B infections



IVD Distributors for CTK

CTK is one of the fastest growing manufacturers in the IVD industry, currently distributing diagnostic test kits in over 120 countries worldwide. We are poised to rapidly expand our distribution network into new markets and increase market share where we have an existing presence. To discuss possible distributor relationships, contact our sales team at info@ctkbiotech.com.





Gastrointestinal

TYPHOID
H. PYLORI
CHOLERA

ROTAVIRUS
ADENOVIRUS

Diseases that affect the gastrointestinal system are caused by a host of bacterial, viral and parasitic organisms that cause gastroenteritis, an inflammation of the gastrointestinal tract involving both the stomach and the small intestine. When symptoms point to a possible gastrointestinal infection, diagnosis can be confirmed through laboratory tests that include detecting antigen in stool specimens or antibodies circulating in the blood. In certain settings where a potential for epidemic outbreaks exists, rapid diagnosis provides important information for implementing infection control measures.

OnSite Rapid Tests are available for a full range of gastrointestinal diseases. Recently added tests include the *OnSite* Rotavirus Ag and Rota/Adeno Ag Rapid Tests to detect and differentiate between two of the leading causes of severe diarrheal diseases in children under the age of 5 years. Combined with other *OnSite* Rapid Tests, differential diagnosis of diarrheal diseases can be made rapidly by excluding particular causative agents. The *OnSite* gastrointestinal line provides a non-invasive test method and rapid, easy to interpret results, three benefits over traditional testing methods.

OnSite Rapid Test Kits

Catalog # Product

R0160C Typhoid IgG/IgM Rapid Test [CE](#)

R0161C Typhoid IgG/IgM Combo Rapid Test [CE](#)

R0191C H. pylori Ab Combo Rapid Test [CE](#)

R0191S H. pylori Ab Combo Rapid Test (strip) [coming soon](#)

R0192C H. pylori Ag Rapid Test [CE](#)

R0192S H. pylori Ag Rapid Test (strip) [CE](#)

R0130C Cholera Ag Rapid Test [CE](#)

R0194C Rotavirus Ag Rapid Test [CE](#)

R0196C Rota/Adeno Ag Rapid Test [CE](#)

Specimen

S, P

S, P & WB

S, P & WB

Fecal

Fecal

Fecal

Fecal

Fecal

Description

Result in 15 minutes allows immediate treatment initiation

Detects IgG and IgM to S.e. Typhi & Paratyphi in the same test

Detects Abs for initial screening of *H. pylori* infection history

Detects Ag shed in the stool, indicative of active infection

Detects Ag shed in the stool, indicative of active infection

Identifies O1 and O139 subtypes of *V. cholerae*

Uses a pair of specific antibodies for detection of rotavirus Ag

3 line test to distinguish rotavirus and adenovirus infections

Positivia External Control Kits

Catalog # Product

C0191 H. pylori Ag Rapid Test Control Kit





Biomarkers

FOB
PSA
TROPONIN I

Valid and specific biomarkers can have a major impact on the diagnosis of a variety of disorders and diseases, allowing early diagnosis which may influence the patient's prognosis. The usefulness of biomarkers in cancer diagnostics for screening and monitoring treatment response is an area of particular interest for the development of *in vitro* diagnostic tests. In addition to cancer screening, biomarkers have proven particularly useful for diagnosing acute coronary events because responding with appropriate medical treatment relies on a rapid result, and electrocardiogram changes may be absent or nonspecific.

OnSite Rapid Tests detect well-characterized biomarkers including fecal occult blood (FOB), prostate-specific antigen (PSA) and Troponin I. FOB tests are used to detect bleeding caused by a number of gastrointestinal disorders including colorectal cancer, polyps, colitis and diverticulitis. PSA is often elevated in patients with prostate cancer, detectable months or years before other clinical symptoms are present, and is used for initial screening and to monitor recurrence. Troponin I, a protein released only when myocardial damage occurs, is a sensitive and specific marker of acute coronary syndrome (ACS) including myocardial infarction.

OnSite Rapid Test Kits

Catalog #	Product
R2010C	FOB Rapid Test CE
R2011C	FOB-Hi Rapid Test CE
R2002C	PSA Semi-quantitative Rapid Test
R3001C	Troponin I Rapid Test CE
R3002C	Troponin I Combo Rapid Test CE

Specimen	Description
Fecal	Detects fecal occult blood ≥ 50 ng/mL Detects fecal occult blood ≥ 25 ng/mL
S, P & WB	Detects prostate-specific antigen ≥ 4 ng/mL
S, P S, P & WB	Detects elevated Troponin I within 10 minutes Compatibility with whole blood specimen allows use in field

Positivia External Control Kits

Catalog #	Product
C2011	FOB Rapid Test Control Kit



Product Inquiries

CTK is continuously developing new products and technologies in response to global health needs. As the developer and manufacturer of our diagnostic test kits, we are capable of localizing products for your specific market. If you identify an unmet diagnostic need in your region send an inquiry to info@ctkbiotech.com.





Sexually Transmitted

CHLAMYDIA
GONORRHEA
HIV
SYPHILIS

Sexually transmitted infections have important implications for public health throughout the world. Although many sexually transmitted diseases are treatable, they frequently go undiagnosed due to the silent and asymptomatic nature of the diseases in their early stages. However, undiagnosed and untreated infections can cause serious long-term complications. Additional concerns include over-treatment of suspected infections leading to widespread antibiotic resistance and infected patients never receiving treatment as they fail to return for their test results. For these reasons, accurate and affordable rapid screening tests are needed for the management of sexually transmitted infections.

OnSite Rapid Tests provide a solution to this need by offering simple, affordable alternatives to time consuming, traditional diagnostic methods. *OnSite* Rapid Tests can be performed in a variety of point-of-care settings by minimally trained personnel providing access to screening even in geographically limiting areas. The short time to result ensures patients receive their results at the time of the initial visit allowing integration of appropriate treatment, counseling and follow up testing. The high sensitivity and specificity of CTK's tests for sexually transmitted diseases allow early detection to prevent disease progression.

OnSite Rapid Test Kits

Catalog #	Product	Specimen	Description
R0080C	Chlamydia Ag Rapid Test	Swab	2 line test for <i>C. trachomatis</i> Ag
R0085S	Gonorrhea Rapid Test (strip) CE	Swab	Detects oxidase activity of <i>N. gonorrhoeae</i>
R0011C	HIV 1/2 Ab Plus Combo Rapid Test	S, P & WB	Double antigen based detection method for increased sensitivity
R0015C	HIV 1+2 Ab Plus Combo Rapid Test	S, P & WB	Utilizes gp120-41 antigen to detect HIV-1+2 Abs
R0018C	HIV Ag/Ab 4th Gen. Rapid Test	S, P & WB	Detects p24 Ag & total Abs to HIV-1+2 including subtype O
R0035C	HIV/Syphilis Ab Combo Rapid Test	S, P & WB	3 line test for HIV-1+2 and Syphilis Ab
R0030C	Syphilis Ab Rapid Test CE	S, P	Treponemal test for direct detection of Syphilis Ab
R0030S	Syphilis Ab Rapid Test (strip) CE	S, P	Treponemal test for direct detection of Syphilis Ab
R0031C	Syphilis Ab Combo Rapid Test CE	S, P & WB	Highly sensitive Ab detection in all stages of disease

Positivia External Control Kits

Catalog #	Product
C0191	HIV-1 P24 Ag Rapid Test Control Kit

ELISA Kits

Catalog #	Product
E0410	HIV 1+2 Ab ELISA Kit
E0420	HIV 1+2 Ag-Ab ELISA Kit http://www.kimhung.vn
E0610	Syphilis Ab ELISA Kit CE





Hormone/Neonatal

TOXO
RUBELLA
CMV
HSV

hCG
TSH-T3-T4

The detection of hormones at certain levels aids in diagnosing a number of conditions including pregnancy and thyroid disorders. In healthy patients, hCG in urine provides an early indication of pregnancy, appearing approximately 8 days after fertilization has occurred and peaking 7-12 weeks after the first day of the last menstrual period. Thyroid hormones, including TSH, T3 and T4, exert powerful and essential regulatory influences on growth, differentiation and cellular metabolism. Together, these three markers are important factors in the diagnosis of thyroid diseases, monitoring both patients under treatment for hyperthyroidism and patients who have discontinued anti-thyroid drug therapy.

During pregnancy, TORCH infections can be spread from a woman to her developing fetus and can cause severe damage to the fetus and congenital birth defects. The immune status and diagnosis of TORCH infections are typically made by serological testing to help determine the risk for transmission. IgG detection is used to determine if a person has been previously exposed to the pathogen. If it is necessary to try to estimate the time of infection, which is of particular importance for Toxo and CMV, a test which detects IgM is also used to discriminate between primary and recurrent infections.

OnSite Rapid Test Kits

Catalog # Product

R0233C Toxo IgG/IgM Rapid Test
 R0233S Toxo IgG/IgM Rapid Test (strip)
R0234C Toxo IgG/IgM Combo Rapid Test

R0243C Rubella IgG/IgM Rapid Test **coming soon**

R0223C Duo CMV IgG-IgM Rapid Test
 R0224C CMV IgG/IgM Rapid Test **coming soon**

R0203C HSV-1 IgG/IgM Rapid Test **coming soon**
 R0213C HSV-2 IgG/IgM Rapid Test **coming soon**

R0253C TORCH Panel Rapid Test **coming soon**

R1000S hCG Urine Rapid Test (strip) **CE**
 R1001C hCG Combo Rapid Test **CE**
 R1001S hCG Combo Rapid Test (strip) **CE**

Specimen

S, P
 S, P
S, P & WB

S, P

Urine
 S, Urine
 S, Urine

Description

3 line test to detect and differentiate IgG & IgM to *T. gondii*
 3 line test to detect and differentiate IgG & IgM to *T. gondii*
Rapid time to result for *T. gondii* infection screening

Two panel test for IgM & IgG to CMV

Simple test procedure to detect hCG in urine specimens
 hCG detection at concentrations ≥ 10 or 25 mIU/mL
 hCG detection at concentrations ≥ 10 or 25 mIU/mL



ELISA Kits www.kimhung.vn

Catalog # Product

E0230 Toxo IgM ELISA Kit
 E0231 Toxo IgG ELISA Kit

E1030 TSH ELISA Kit **CE**
 E1010 Total T3 ELISA Kit **CE**
 E1011 Free T3 ELISA Kit **coming soon**
 E1020 Total T4 ELISA Kit **CE**
 E1021 Free T4 ELISA Kit **coming soon**



Certifications



ISO 13485:2003

ISO 13485:2003 is an internationally recognized standard that ensures that the manufacturer can demonstrate its ability to consistently deliver quality medical devices and related services that meet customer requirements and applicable regulatory requirements.

FDA cGMP

The US FDA issues guidelines for Quality System Regulation to address essential elements such as design, production and distribution of finished products. The quality systems for FDA-regulated products (food, drugs, biologics, and devices) are known as current good manufacturing practices (cGMP's).

CE Mark

Most of CTK's diagnostic test kits are CE marked. In order for products to be placed on the European market, they must meet the requirements of the relevant product directives. With the CE marking, products may be freely distributed and sold throughout the EU.



<http://www.kimhung.vn>



SCAN TO FIND OUT MORE ABOUT OUR DIAGNOSTIC SOLUTIONS OR VISIT CTKBIOTECH.COM



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10110 Mesa Rim Road | San Diego, CA 92121 USA | Tel: 858.457.8698 | Fax: 858.535.1739

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