



[510\(k\)](#) | [Registration & Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)
[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [Recalls](#) | [Guidance](#) | [Standards](#)

1 registered establishments meeting your search criteria returned - **Establishment Registration Name** : Health Chem Diagnost **Owner Operator Number** : 9060349 **Owner Operator Name** : Health Chem Diagnost **Establishment Type** : Manufacturer

New Search		Help Download Files More About Registration & Listing	
Name	State/Country	Registration Number	Current Registration Yr
HEALTH CHEM DIAGNOSTICS LLC	FL/USA	1048532	2009
<ul style="list-style-type: none"> • DISCS, STRIPS AND REAGENTS, MICROORGANISM DIFFERENTIATION - MICROORGANISM DIFFERENTIATION: STRIPS AND REAGENTS: DISCS 			Manufacturer
<ul style="list-style-type: none"> • ANTISERUM, POSITIVE AND NEGATIVE FEBRILE ANTIGEN CONTROL SERUM - POSITIVE AND NEGATIVE FEBRILE ANTI: ANTISERUM: GEN CONTROL SERUM 			Manufacturer
<ul style="list-style-type: none"> • PLASMA, COAGULASE, HUMAN, HORSE AND RABBIT - COAGULASE: HORSE AND RABBIT; HUMAN: PLASMA 			Manufacturer
<ul style="list-style-type: none"> • TETRAZOLIUM INT DYE-DIAPHORASE, LACTATE DEHYDROGENASE - LACTATE DEHYDROGENASE: TETRAZOLIUM INT DYE-DIAPHORASE 			Manufacturer
<ul style="list-style-type: none"> • HYDRAZONE COLORIMETRY, ALT/SGPT - , ALT: GPT: HYDRAZONE COLORIMETRY 			Manufacturer
<ul style="list-style-type: none"> • NADH OXIDATION/NAD REDUCTION, ALT/SGPT - , ALT: GPT: NADH OXIDATION/NAD REDUCTION 			Manufacturer
<ul style="list-style-type: none"> • TRYPTOPHAN MEASUREMENT (COLORIMETRIC), GLOBULIN - GLOBULIN: TRYPTOPHAN MEASUREMENT (COLORIMETRI 			Manufacturer
<ul style="list-style-type: none"> • ENZYMATIC ESTERASE--OXIDASE, CHOLESTEROL - CHOLESTEROL: ENZYMATI 			Manufacturer
<ul style="list-style-type: none"> • LIEBERMAN-BURCHARD/ABELL-KENDALL, COLORIMETRIC, CHOLESTEROL - CHOLESTEROL: COLORIMETRIC: LIEBERMAN-BURCHARD/ABELL-KENDALL 			Manufacturer
<ul style="list-style-type: none"> • LIPASE HYDROLYSIS/GLYCEROL KINASE ENZYME, TRIGLYCERIDES - TRIGLYCERIDES: IDES: LIPASE HYDROLYSIS/GLYCEROL KINASE E 			Manufacturer
<ul style="list-style-type: none"> • ACID, ALPHA-KETOBTYRIC AND NADH (U.V.), HYDROXYBUTYRIC DEHYDROGENASE - ALPHA-KETOBTYRIC AND NADH (U.V.): HYDROXYBUTYRIC DEHYDROGENASE: ACID 			Manufacturer
<ul style="list-style-type: none"> • RADIOIMMUNOASSAY, DESOXYCORTICOSTERONE - DESOXYCORTICOSTERONE: RADIOIMMUNOASSAY 			Manufacturer
<ul style="list-style-type: none"> • RADIOIMMUNOASSAY, FOLLICLE-STIMULATING HORMONE - FOLLICLE- 			Manufacturer

STIMULATING HORMONE: RADIOIMMUNOASSAY	
<ul style="list-style-type: none"> • RADIOIMMUNOASSAY, IMMUNOREACTIVE INSULIN - IMMUNOREACTIVE INSULIN: RADIOIMMUNOASSAY 	Manufacturer
<ul style="list-style-type: none"> • RADIOIMMUNOASSAY, PROGESTERONE - PROGESTERONE: RADIOIMMUNOASSAY 	Manufacturer
<ul style="list-style-type: none"> • RADIOIMMUNOASSAY, TOTAL TRIIODOTHYRONINE - TOTAL TRIIODOTHYRONINE: RADIOIMMUNOASSAY 	Manufacturer
<ul style="list-style-type: none"> • RADIOASSAY, TRIIODOTHYRONINE UPTAKE - TRIIODOTHYRONINE UPTAKE: RADIOASSAY 	Manufacturer
<ul style="list-style-type: none"> • WHOLE HUMAN SERUM, ANTIGEN, ANTISERUM, CONTROL - ANTIGEN: ANTISERUM: CONTROL: WHOLE HUMAN SERUM 	Manufacturer
<ul style="list-style-type: none"> • ALBUMIN, ANTIGEN, ANTISERUM, CONTROL - ANTIGEN: ANTISERUM: CONTROL: ALBUMIN 	Manufacturer
<ul style="list-style-type: none"> • TOTAL SPINAL-FLUID, ANTIGEN, ANTISERUM, CONTROL - ANTIGEN: ANTISERUM: CONTROL: TOTAL SPINAL-FLUID 	Manufacturer
<ul style="list-style-type: none"> • NAD REDUCTION/NADH OXIDATION, LACTATE DEHYDROGENASE - LACTATE DEHYDROGENASE: NAD REDUCTION/NADH OXIDATION 	Manufacturer
<ul style="list-style-type: none"> • PRODUCTS, RED-CELL LYSING PRODUCTS - RED-CELL LYSING PRODUCTS: PRODUCTS 	Manufacturer
<ul style="list-style-type: none"> • DILUENT, BLOOD CELL - BLOOD CELL: DILUENT 	Manufacturer
<ul style="list-style-type: none"> • BIURET (COLORIMETRIC), TOTAL PROTEIN - TOTAL PROTEIN: BIURET (COLORIMETRIC) 	Manufacturer
<ul style="list-style-type: none"> • WHOLE BLOOD PLASMA, ANTIGEN, ANTISERUM, CONTROL - ANTIGEN: ANTISERUM: CONTROL: WHOLE BLOOD PLASMA 	Manufacturer
<ul style="list-style-type: none"> • CHROMATOGRAPHIC, PHOSPHOLIPIDS - PHOSPHOLIPIDS: CHROMATOGRAPHIC 	Manufacturer
<ul style="list-style-type: none"> • KIT, TEST, PREGNANCY, HCG, OVER THE COUNTER - Diagnosis Gold Pregnancy Test; Diagnosis Stick; EVATEST Wand; Event test wand; hCG Pregnancy One Step Wand; One Step One Minute Pregnancy Test; PDQ Pregnancy Test; Ultra Pregnancy Test 	Contract Manufacturer; Manufacturer; Repackager/Relabeler
<ul style="list-style-type: none"> • SINGLE (SPECIFIED) ANALYTE CONTROLS (ASSAYED AND UNASSAYED) - Critic; Critic -C; Dimension Control; UroQual; UroQuant 	Contract Manufacturer; Manufacturer; Repackager/Relabeler
<ul style="list-style-type: none"> • PLASMA, CONTROL, NORMAL - Repaplasma Normal 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • DRUG MIXTURE CONTROL MATERIALS - Urol-Quant Urine Controls 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • REAGENT & CONTROL, PARTIAL THROMBOPLASTIN TIME - Repaplastin APT & Repaplastin 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • SYSTEM, TEST, HUMAN CHORIONIC GONADOTROPIN - One step one minute, Ultra, Evast 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • URINALYSIS CONTROLS (ASSAYED AND UNASSAYED) - Urol Quant/Urol Qual Urine Controls 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • IGA, ANTIGEN, ANTISERUM, CONTROL - Citric-C Controls; Ima-Trol Immunoassay Controls 	Contract Manufacturer; Manufacturer

IGE, ANTIGEN, ANTISERUM, CONTROL - Citric-C Controls: Ima-Trol Immunoassay Controls	Contract Manufacturer; Manufacturer
• PLASMA, COAGULATION FACTOR DEFICIENT - Rapaplasma Abnormal	Contract Manufacturer; Manufacturer
• CALIBRATOR, MULTI-ANALYTE MIXTURE - Critic-C Controls: Ima-Trol Immunoassay Controls	Contract Manufacturer; Manufacturer
• IGM, ANTIGEN, ANTISERUM, CONTROL - Critic-C Controls: Ima-Trol Immunoassay Controls	Contract Manufacturer; Manufacturer
• GLUCOSE OXIDASE, GLUCOSE - One Step Whole Blood Glucose Test	Contract Manufacturer; Manufacturer
• STANDARDS AND CONTROLS, HEMOGLOBIN, NORMAL AND ABNORMAL - Critic Hemoglobin	Contract Manufacturer; Manufacturer
• ANTITHROMBIN III, TWO STAGE CLOTTING TIME ASSAY - Rapaplastin APT & Repaplastin	Contract Manufacturer; Manufacturer
• MULTI-ANALYTE CONTROLS, ALL KINDS (ASSAYED) - Critic ARS Multianalyte Controls: Critic-C Controls: Ima-Trol Immunoassay Controls	Contract Manufacturer; Manufacturer
• CALIBRATOR, PRIMARY - Ima-Trol Immunoassay Controls	Contract Manufacturer; Manufacturer
• RADIOIMMUNOASSAY, HUMAN CHORIONIC GONADOTROPIN - Event Test Strip HCG	Contract Manufacturer; Manufacturer
• KIT, TEST, PREGNANCY, HCG, OVER THE COUNTER - Evatest Strip	Contract Manufacturer; Manufacturer
• KIT, TEST, PREGNANCY, HCG, OVER THE COUNTER - HCG Pregnancy One Step Test Strip	Contract Manufacturer; Manufacturer
• RADIOIMMUNOASSAY, HUMAN CHORIONIC GONADOTROPIN - HCG Diuelent Reagent: One Step Pregnancy	Contract Manufacturer; Manufacturer
• RADIOIMMUNOASSAY, LUTEINIZING HORMONE - One Step LH Test	Contract Manufacturer; Manufacturer
• METHOD, ENZYMATIC, GLUCOSE (URINARY, NON-QUANTITATIVE) - Uri-Test Glucose in Urine	Contract Manufacturer; Manufacturer
• DIAZO (COLORIMETRIC), NITRITE (URINARY, NON-QUANT) - Uri-Test - Nitrite in Urine Test	Contract Manufacturer; Manufacturer
• INDICATOR METHOD, PROTEIN OR ALBUMIN (URINARY, NON-QUANT.) - Uri-Test Protein in Urine	Contract Manufacturer; Manufacturer
• ENZYME IMMUNOASSAY, BARBITURATE - Barbituate Test: One Step Unie Drug of Abuse:	Contract Manufacturer; Manufacturer
• ENZYME IMMUNOASSAY, BENZODIAZIPINE - Benzodiazepine Assay: One Step Urine Drug of Abuse:	Contract Manufacturer; Manufacturer
• ENZYME IMMUNOASSAY, AMPHETAMINE - Methamphetamine Test: One Step Urine Drubv of Abuse	Contract Manufacturer; Manufacturer
• ENZYME IMMUNOASSAY, PHENCYCLIDINE - One Step Urine Drug of Abuse:	Contract Manufacturer; Manufacturer
• ENZYME IMMUNOASSAY, AMPHETAMINE - Amphetamine Test: One Step Urine Drug of Abuse:	Contract Manufacturer; Manufacturer
• ENZYME IMMUNOASSAY, CANNABINOIDS - Cannabinoid Test: One Step	Contract Manufacturer;

Drug of Abuse	Manufacturer
<ul style="list-style-type: none"> • ENZYME IMMUNOASSAY, COCAINE AND COCAINE METABOLITES - Cocaine Test: One Step Urine Drug of Abuse: 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • ENZYME IMMUNOASSAY, OPIATES - One Step Urine Drug of Abuse: Opiate Test: Opium/Heroin/Morphine 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • PLATELET FACTOR 4 RADIOIMMUNOASSAY - Heparin Piafa PF4 Antibody Test 	Contract Manufacturer; Manufacturer; Repackager/Relabeler; U.S. Manufacturer of Export Only Devices
<ul style="list-style-type: none"> • DEVICE, SEMEN ANALYSIS - Male Fertility Test 	Contract Manufacturer; Manufacturer; U.S. Manufacturer of Export Only Devices
<ul style="list-style-type: none"> • DEVICES, BREATH TRAPPING, ALCOHOL - 	Contract Manufacturer; Manufacturer; Repackager/Relabeler
<ul style="list-style-type: none"> • ACTIVATED PARTIAL THROMBOPLASTIN - Repaplistin APT & Rapaplistin 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • ELECTROLYTE CONTROLS (ASSAYED AND UNASSAYED) - Critic: Ima-Trol Immunoassay Control 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • ENZYME CONTROLS (ASSAYED AND UNASSAYED) - 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • REAGENT, THROMBOPLASTIN AND CONTROL - Repaplistin 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • CONTROL, PLASMA, ABNORMAL - Repaplasma Abnormal 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • PLASMA, COAGULATION CONTROL - Repaplasma Normal 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • MULTI-ANALYTE CONTROLS, ALL KINDS (ASSAYED) - Urol-Quant Urine Controls 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • CALIBRATOR, MULTI-ANALYTE MIXTURE - Citric-ARS Multianalyte Calibrators 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • MULTI-ANALYTE CONTROLS, ALL KINDS (ASSAYED) - Ima-Trol Immunoassay Controls 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • URINALYSIS CONTROLS (ASSAYED AND UNASSAYED) - Urol-Quant Urine Contols 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • MULTI-ANALYTE CONTROLS, ALL KINDS (ASSAYED) - Citric C Level I & Li 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • MULTI-ANALYTE CONTROLS, ALL KINDS (ASSAYED) - Multi-Analyte Controls, all Kinds 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • NADH OXIDATION/NAD REDUCTION, ALT/SGPT - Alt-30, 60 and 100 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • RADIOIMMUNOASSAY, HUMAN CHORIONIC GONADOTROPIN - HCG Pregnancy One Step Test Strip 	Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> • GLUCOSE OXIDASE, GLUCOSE - Dimension - WBG 	Contract Manufacturer; Manufacturer

<ul style="list-style-type: none">• ENZYMATIC ESTERASE--OXIDASE, CHOLESTEROL - Cholesterol Complete: Dimension Whole Blood Cholesterol
--

Contract Manufacturer; Manufacturer
--

Database Updated 05/07/2009

[CDRH Home Page](#) | [CDRH A-Z Index](#) | [Contact CDRH](#) | [Accessibility](#) | [Disclaimer](#)
[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [HHS Home Page](#)

Center for Devices and Radiological Health / CDRH