

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k050536

B. Purpose for Submission: Notification of intent to manufacture and market the device: Quest Diagnostics Immunoassay/TDM Controls

C. Measurand:

- 17- α -Hydroxyprogesterone
- Acetaminophen
- Aldosterone
- Alpha Fetoprotein (AFP)
- Amikacin
- Androstenedione
- Caffeine
- Carbamazepine
- CEA
- Chloramphenicol
- Cortisol
- C-Peptide
- DHEA Sulfate
- Digoxin
- Disopyramide
- Estradiol
- Estriol, Free
- Ethosuximide
- Ferritin
- Folate
- FSH
- Gastrin
- Gentamicin
- Homocysteine
- hCG
- hGH
- Immunoglobulin E (IgE)
- Insulin

- Lidocaine
- Lithium
- LH
- NAPA
- PTH, Intact
- Phenobarbital
- Phenytoin
- Primidone
- Procainamide
- Progesterone
- Prolactin
- PAP
- PSA
- PSA, Free
- Quinidine
- Salicylate
- T3, Free
- T3, Total
- T4, Free
- T4, Total
- Testosterone
- Theophylline
- Tobramycin
- TSH
- Valproic Acid
- Vancomycin
- Vitamin B12

D. Type of Test:

Quality Control Material

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Proprietary – Quest Diagnostics Immunoassay/TDM Controls
Established – Multi-Analyte Controls, Assayed and Unassayed

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1660

2. Classification:

Class I

3. Product code:

JJY

4. Panel:

75, Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

Quest Diagnostics Immunoassay/TDM Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures listed in this package insert.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Not applicable

I. Device Description:

Quest Diagnostics Immunoassay/TDM Control is prepared from human serum with added constituents of human and animal origin, chemicals and therapeutic drugs. The product is provided in lyophilized form for increased

stability. Each level of control contains 4 – 5ml bottles.

Each human donor unit used to manufacture this control was tested by FDA accepted methods and found to be non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bio-Rad Laboratories Lyphochek Immunoassay Plus Control

2. Predicate 510(k) number(s):

k981532

3. Comparison with predicate:

Characteristics	Quest Diagnostics Immunoassay/TDM Control (New Device)	Bio-Rad Laboratories Lyphochek Immunoassay Plus Control (Predicate Device K981532)
Similarities		
Intended Use	Quest Diagnostics Immunoassay/TDM Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Lyphochek Immunoassay Plus Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Form	Lyophilized	Lyophilized
Matrix	Human Serum	Human Serum
Preservatives	Does not Contains preservatives	Does not Contains preservatives
Storage (Unopened)	2°C to 8°C Until expiration date	2°C to 8°C Until expiration date
Differences		
Reconstituted Vial Claim	7 days at 2 to 8°C with the following exceptions: (1) C-Peptide, Folate and PSA 3 days (2) Gastrin, Free PSA and Intact PTH assay immediately	7 days at 2°C to 8°C with the following exceptions: (1) Folate and PSA 3 days, (2) C-Peptide 1 day, (3) Intact PTH 16 hours, (4) ACTH, Calcitonin, Gastrin and Free PSA assay immediately
After Reconstituting and Freezing	No claims	All analytes 30 days at -10 to -20°C
Analytes	Contains the following analytes: <ul style="list-style-type: none"> • 17-α-Hydroxyprogesterone • Acetaminophen • Aldosterone • Alpha Fetoprotein (AFP) • Amikacin • Androstenedione • Lidocaine • Lithium • LH • NAPA • PTH, Intact • Phenobarbital 	Contains the following analytes: <ul style="list-style-type: none"> • 11-Deoxycortisol • 17-α-Hydroxyprogesterone • Acetaminophen • ACTH) • Alpha Fetoprotein (AFP) • Amikacin • Immunoglobulin E (IgE) • Insulin • Lidocaine • Lithium • LH • NAPA

Characteristics	Quest Diagnostics Immunoassay/TDM Control (New Device)		Bio-Rad Laboratories Lyphochek Immunoassay Plus Control (Predicate Device K981532)	
	<ul style="list-style-type: none"> •Caffeine •Carbamazepine •CEA •Chloramphenicol •Cortisol •C-Peptide •DHEA Sulfate •Digoxin •Disopyramide •Estradiol •Estriol, Free •Ethosuximide •Ferritin •Folate •FSH •Gastrin •Gentamicin •Homocysteine •hCG •hGH •Immunoglobulin E (IgE) •Insulin 	<ul style="list-style-type: none"> •Phenytoin •Primidone •Procainamide •Progesterone •Prolactin •PAP •PSA •PSA, Free •Quinidine •Salicylate •T3, Free •T3, Total •T4, Free •T4, Total •Testosterone •Theophylline •Tobramycin •TSH •Valproic Acid •Vancomycin •Vitamin B12 	<ul style="list-style-type: none"> • Aldosterone • Amitriptyline • Androstenedione • Caffeine • Calcitonin • Carbamazepine, Free • Carbamazepine • CEA • Chloramphenicol • Cortisol • C-Peptide • DHEA Sulfate • Digoxin • Disopyramide • Cyclosporine • Desipramine • DHEA • Estradiol • Estriol, Free • Estriol, Total • Estrogens, Total • Ethosuximide • Ferritin 	<ul style="list-style-type: none"> • Netilmicin • Nortriptyline • PTH • Phenobarbital • Phenytoin • Phenytoin, Free • Primidone • Procainamide • Progesterone • Prolactin • PAP • Propanolol • PSA • PSA, Free • Quinidine • Salicylate • T3 Free • T3 Total • T3 Uptake • T4 Free • T4 Total • TCA Screen • Testosterone
	<ul style="list-style-type: none"> • <u>Does not Contains the following analytes:</u> • 11-Deoxycortisol • Aldosterone • Amitriptyline • Calcitonin • Carbamazepine, Free • Cyclosporine* • Desipramine • DHEA • Estriol, Total • Estrogens, Total • Flecainide • 25-Hydroxy Vitamin D • Angiotensin I • Fructosamine • Glucagon • Iron 	<ul style="list-style-type: none"> • <u>TIBC</u> • HCG-Beta Subunit • Imipramine • Netilmicin • Nortriptyline • Phenytoin, Free • Propanolol • T3 Uptake • TCA Screen • Testosterone, Free • Valproic Acid, Free • Immunoglobulin A (IgA) • Immunoglobulin G (IgG) • Immunoglobulin M (IgM) • Somatomedin-C • TBG • Thyroglobulin 	<ul style="list-style-type: none"> • Folate • Flecainide • FSH • Gastrin • Gentamicin • hCG and hCG-Beta Subunit • hGH • Imipramine • 25-Hydroxy Vitamin D • Angiotensin I • Fructosamine • Glucagon • Iron • TIBC • Homocysteine 	<ul style="list-style-type: none"> • Testosterone, Free • Theophylline • Tobramycin • TSH • Valproic Acid • Valproic Acid, Free • Vancomycin • Vitamin B12 • Immunoglobulin A (IgA) • Immunoglobulin G (IgG) • Immunoglobulin M (IgM) • Somatomedin-C • TBG • Thyroglobulin

K. Standard/Guidance Document Referenced (if applicable):

No standard or guidance document was referenced.

L. Test Principle:

Not Applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not Applicable

b. Linearity/assay reportable range:

Not Applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Stability studies have been performed to determine the open vial stability and shelf life for the Quest Diagnostics Immunoassay/TDM Control. Product claims and a summary of the protocols used to establish claims are as follows:

- Open vial Stability: 7days when stored tightly capped at 2 to 8°C with the following exceptions: C-Peptide, Folate and PSA are stable for 3 days and Gastrin, Free PSA and Intact PTH should be assayed immediately after reconstitution.
- Shelf Life: 36 months when stored at 2 to 8 °C

All supporting data is retained on file at Bio-Rad Laboratories.

The mean value presented in the Quest Diagnostics Immunoassay/TDM Control product insert is generated by four Quest Diagnostics Laboratories. Mean values were derived from replicate measurements from various Quest Laboratories and are specific for each lot of product.

Quest Diagnostics Immunoassay/TDM Control Value assignment protocol requires running all three levels of control lot five times for five testing days resulting in 25 results per analyte. Proficiency testing performance should be such that average SDI<1.0 and no SDI>3.0

d. Detection limit:

Not Applicable

e. Analytical specificity:

Not Applicable

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not Applicable

b. Matrix comparison:

Not Applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable

b. Clinical specificity:

Not Applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not Applicable

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:

Not Applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.