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Nonstandard Laboratory Test Panels

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Policy

Scope of Policy

This Clinical Policy Bulletin addresses nonstandard laboratory test panels.

1. Experimental, Investigational, or Unproven

Aetna considers laboratory test panels experimental, investigational, or unproven if they include nonstandard tests that have no proven value. Laboratory test panels may also be considered experimental, investigational, or unproven if they include standard tests that are performed for persons without specific signs and symptoms warranting performance of the test and for indications that are not established.

1. Aeron Life Cycles

Aetna considers the following test panels from Aeron Life Cycles experimental, investigational, or unproven because of insufficient evidence:

- BPAssay
- Saliva Analysis
- Urine Bone Marker.

2. Alletess Medical Laboratory

Aetna considers the following tests from Alletess Medical Laboratory experimental, investigational, or unproven because of insufficient evidence:

- Hytex Enzyme Immunoassay
- Food Sensitivity Testing Panel
- Vegetarian 80 IgG Food Pane
- Pediatric 80 IgG Food Panel
- Gastrointestinal Panel
- Protein Sensitivity Panel
- Casein/Gluten Screen
- Candida Immune Complex
- Candida Profile
- Microflora Immune Competency Test
- Comprehensive 96 IgG Immune Panel
- Comprehensive 184 IgG Immune Panel.

3. BioHealth

Aetna considers the following BioHealth Test Panels experimental, investigational, or unproven because of insufficient evidence:

- Functional Adrenal Stress Profiles, Saliva
- Female Hormone Profiles, Saliva
- Melatonin Biorhythm Profile, Saliva
- DHEA-s Average. Saliva
- Expanded Circadian Rhythm, Saliva
- Metabolic Assessment Profile, Urine
- GI Pathology Screen, Stool
- Intestinal Barrier Function Screen, Salivary
- Celiac/Gluten Sensitive Enteropathy Profile, Blood/Saliva
- Expanded Chemistry Profile, Blood
- Coronary Risk Screen
- Glycemic Control Screen.

4. DiagnosTechs

Aetna considers the following DiagnosTechs Laboratory Test Panels experimental, investigational, or unproven because of insufficient evidence of their clinical value:

- Adrenal Stress Index
- Bone Health Panel
- Female Hormone Panel
- Food Intolerance Panel
- Gastrointestinal Health Panel
- Male Hormone Panel
- Postmenopause and Perimenopause Panels.

5. Doctor's Data Lab

Aetna considers the following Doctor's Data Lab Panels experimental, investigational, or unproven unless otherwise noted, because of insufficient evidence of their clinical value:

1. Nutritional

- Fatty Acids; Erythrocytes
- Plasma Amino AcidsFootnote1*
- Urine Amino AcidsFootnote1*
- Urine FluorideFootnote2**
- Urine Halides
- Urine Halides; Pre and Post Loading
- Urine Iodine
- Urine Iodine; Pre and Post LoadingFootnote3***

Notes:

Footnote1* Plasma and urinary amino acids may be medically necessary for screening neonates and for testing other persons with signs and symptoms of primary or secondary aminoacidopathies.

Footnote2** Urine fluorides may be medically necessary for persons with signs and symptoms of fluoride toxicity.

Footnote3*** Urine iodine may be medically necessary for persons with signs and symptoms of iodine deficiency.

2. Clinical Microbiology

- Bacteriology Culture, Stool
- Comprehensive Clostridium Culture, Stool
- Comprehensive Parasitology x1, Stool
- Comprehensive Parasitology x2, Stool

- Comprehensive Parasitology x3, Stool
- Comprehensive Stool Analysis
- Comprehensive Stool Analysis w/Parasitology x1
- Comprehensive Stool Analysis w/Parasitology x2
- Comprehensive Stool Analysis w/Parasitology x3
- Comprehensive Vaginosis Profile
- Intestinal Permeability
- Lysozyme Stool
- Microbiology Profile, Stool
- Parasitology x1, Stool
- Parasitology x2, Stool
- Parasitology x3, Stool
- Secretory IgA, stool
- Stool Chemistry
- Stool Yeast Culture

3. Toxic and Essential Elements

- Comprehensive Blood Elements
- Fecal Metals
- Hair Elements
- Hair Toxic Element Exposure Profile
- Red Blood Cell (RBC) Elements
- Urine Toxic & Essential Elements
- Urine Toxic Metals
- Whole Blood Chromium & Vanadium
- Whole Blood Elements

4. Drinking Water Analysis

- Comprehensive Drinking Water Analysis
- Drinking Water Analysis

5. Bloodspot

DNA Methylation Pathway, Bloodspot.

6. Cardiovascular

- Cardiovascular Risk Profile
- Comprehensive Cardiovascular Profile
- Oxidized LDL

7. Environmental Exposure/Detoxification

- DNA Methylation Pathway; Whole Blood
- DNA Oxidative Damage Assay
- Glutathione, ErythrocytesFootnote4†
- Hepatic Detox Profile
- Methylation Profile, Plasma
- Urine PorphyrinsFootnote5††

Notes:

Footnote4† Red cell glutathione is considered medically necessary for persons with hemolytic anemia and for persons with signs and symptoms of defects of red blood cell metabolism.

Footnote5†† Measurement of urine porphyrins is considered medically necessary for persons with signs and symptoms of porphyria.

6. Great Plains Laboratory

Aetna considers the following Great Plains Laboratory Test panels experimental, investigational, or unproven because there is insufficient published peer-reviewed evidence of their clinical utility:

- Basic Autism Panel
- Comprehensive Autism Panel
- Basic Tourette's Tics Panel
- Comprehensive Tourette's Tics Panel
- Basic Wellness Panel
- Comprehensive Wellness Panel
- Basic Fibromyalgia and CFS Panel
- Comprehensive Fibromyalgia and CFS Panel
- Basic Mental Health Panel
- Comprehensive Mental Health Panel.

The following Great Plains Laboratory Tests and Panels are considered experimental, investigational, or unproven:

- Advanced Cholesterol Profile
- Amino Acids Plasma Test
- Amino Acids Urine Test
- Comprehensive Fatty Acids Test
- Comprehensive Stool Analysis
- Copper / Zinc Profile
- Full Organic Acids Test (OAT)
- Gluten / Casein Peptides Test
- GPL-TOX Profile (for toxic non-metal chemicals)
- Hormone Panels
- IgG Food Allergy Test with Candida
- Immune Deficiency Profile
- Kryptopyrrole Test
- Metals Fecal Test
- Metals Hair Test
- Metals Red Blood Cell Test
- Metals Urine Test
- Metals Whole Blood Test
- Microbial Organic Acids Test (MOAT)
- MOAT Plus Yeast Culture with Sensitivity Combo
- OAT Plus Amino Acids Urine Test Combo
- OAT Plus IgG Food Allergy Test with Candida Combo
- OAT Plus Yeast Culture with Sensitivity Combo
- Organic Acids Test
- Porphyrins Profile^{Footnote6†††}
- Streptococcus Antibodies Profile
- Yeast Culture and Sensitivity Test, Stool.

Footnote6††† Measurement of urine porphyrins is considered medically necessary for persons with signs and symptoms of porphyria.

7. Moleculera Labs

The following test panel from Moleculera Labs is considered experimental, investigational, or unproven:

Pediatric autoimmune neuropsychiatric disorders associated with group A streptococci (PANDAS)

Cunningham Test Panel.

8. Physicians Lab

Physicians Lab urine panels are considered experimental, investigational, or unproven, including:

- Comprehensive #1 24-hour urine profile
- Comprehensive #2 24-hour urine profile
- Estrogen specific 24-hour urine profile
- Androgen specific 24-hour urine profile
- Cortisol specific 24-hour urine profile
- First morning void profile.

9. ZRT Laboratory

The following test panels from ZRT Laboratory are considered experimental, investigational, or unproven because of insufficient published, peer-reviewed evidence:

- Weight Management Profile, Blood Spot/Saliva
- Fertility Profile, Blood Spot/Saliva
- Dried Urine Metabolites
 - Complete Urine Metabolites
 - Urine Sex Steroid Metabolites
 - Urinary Free Cortisols.

10. Other Laboratories

The following laboratories perform non-standard test panels that are considered experimental, investigational, or unproven; most also perform various standard tests:

- Age Diagnostic Laboratories
- Bio-Center Laboratory (BCL)
- BioLab Medical Unit
- Center for Complex Medical Systems
- Dried Urine Test for Comprehensive Hormones (DUTCH) testing
- Fry Laboratories, LLC
- Genelex Corp.
- Immuno Laboratories
- Immunosciences Lab, Inc.
- IntraCellular Diagnostics, Inc.
- Iverson Genetic Diagnosis
- King James Lab
- LabInterpretation LLC
- Labrix Clinical Services
- Meridian Valley Lab
- Metamatrix Clinical Laboratory
- Molecular Testing Labs (Blackfly Investments, LLC)
- NutriChem Biomedical Testing Laboratory
- PathoGenius Laboratory
- PersonalizedDx Labs
- Pharmasan Labs
- Primex Clinical Laboratories
- RealTime Laboratories, Inc.
- Salveo Diagnostics Advanced Blood/Stool Testing Profiles/Panels
- SpectraCell Laboratories, Inc.
- Trace Minerals International Laboratory
- U.S. BioTek
- YorkTest Laboratories.

2. Related Policies

- CPB 0140 - Genetic Testing
- CPB 0177 - Helicobacter Pylori Infection Testing
- CPB 0215 - Lyme Disease and other Tick-Borne Diseases
- CPB 0249 - Inflammatory Bowel Disease: Serologic Markers and Pharmacogenomic and Metabolic Assessment of Thiopurine Therapy
- CPB 0396 - Gastrointestinal Function: Selected Tests
- CPB 0438 - Obsolete and Unreliable Tests and Procedures
- CPB 0561 - Celiac Disease Laboratory Testing
- CPB 0650 - Polymerase Chain Reaction Testing: Selected Indications
- CPB 0608 - Salivary Tests
- CPB 0691 - Exhaled Breath Tests
- CPB 0715 - Pharmacogenetic and Pharmacodynamic Testing
- CPB 1008 - Metagenomic Next Generation Sequencing Tests for Infectious Diseases

Table:

CPT Codes / HCPCS Codes / ICD-10 Codes

Great Plains Laboratory:

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

Code	Code Description
Other CPT codes related to the CPB:	
80299	Quantitation of therapeutic drug, not elsewhere specified
82108	Aluminum
82131	Amino acids; single, quantitative, each specimen
82139	Amino acids, 6 or more amino acids, quantitative, each specimen
82140	Ammonia
82172	Apolipoprotein, each
82175	Arsenic
82272	Blood, occult, by peroxidase activity (eg, guaiac), qualitative, feces, 1-hyphen3 simultaneous determinations, performed for other than colorectal neoplasm screening
82300	Cadmium
82306	Vitamin D; 25 hydroxy, includes fraction(s), if performed
82310	Calcium; total
82390	Ceruloplasmin
82465	Cholesterol, serum or whole blood, total
82495	Chromium
82507	Citrate
82525	Copper
82530	Cortisol; free
82542	Column chromatography, includes mass spectrometry, if performed (eg, HPLC, LC, LC/MS, LC/MS-hyphenMS, GC, GC/MS-hyphenMS, GC/MS, HPLC/MS), non-hyphen drug analyte(s) not elsewhere specified, qualitative or quantitative, each specimen
82570	Creatinine; other source
82626	Dehydroepiandrosterone (DHEA)
82656	Elastase, pancreatic (EL-hyphen1), fecal, qualitative or semi-hyphen quantitative
82670	Estradiol
82677	Estriol
82679	Estrone
82728	Ferritin
82784	Gammaglobulin (immunoglobulin); IgA, IgD, IgG, IgM, each
82785	Gammaglobulin; IgE
82787	Gammaglobulin (immunoglobulin); immunoglobulin subclasses (eg, IgG1, 2, 3, or 4), each
83015	Heavy metal (eg, arsenic, barium, beryllium, bismuth, antimony, mercury)
83018	Heavy metal (eg, arsenic, barium, beryllium, bismuth, antimony, mercury); quantitative, each
83090	Homocysteine
83150	Homovanillic acid (HVA)
83497	Hydroxyindolacetic acid, 5-hyphen (HIAA)
83516	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method
83519	Immunoassay, analyte, quantitative; by radiopharmaceutical technique (e.g., RIA)
83605	Lactate (lactic acid)
83631	Lactoferrin, fecal; quantitative
83655	Lead

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

Code	Code Description
83695	Lipoprotein (a)
83718	Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)
83735	Magnesium
83785	Manganese
83825	Mercury, quantitative
83883	Nephelometry, each analyte not elsewhere specified
83885	Nickel
83921	Organic acids, single, quantitative
83945	Oxalate
83986	pH; body fluid, not otherwise specified
84100	Phosphorus inorganic (phosphate)
84120	Porphyrins, urine; quantitation and fractionation
84255	Selenium
84285	Silica
84295	Sodium; serum, plasma or whole blood
84402	Testosterone; free
84540	Urea nitrogen, urine
84585	Vanillylmandelic acid (VMA), urine
84591	Vitamin, not otherwise specified
84630	Zinc
84999	Unlisted chemistry procedure
85549	Muramidase
85999	Unlisted hematology and coagulation procedure
86001	Allergen specific IgG quantitative or semiquantitative, each allergen
86141	C-hyphenreactive protein; high sensitivity (hsCRP)
86215	Deoxyribonuclease, antibody
86628	Antibody; Candida
86671	Antibody; fungus, not elsewhere specified
87045	Culture, bacterial; stool, aerobic, with isolation and preliminary examination (eg, KIA, LIA), Salmonella and Shigella species
87046	stool, aerobic, additional pathogens, isolation and presumptive identification of isolates, each plate
87102	Culture, fungi (mold or yeast) isolation, with presumptive identification of isolates; other source (except blood)
87106	Culture, fungi, definitive identification, each organism; yeast
87177	Ova and parasites, direct smears, concentration and identification
87184	Susceptibility studies, antimicrobial agent; disk method, per plate (12 or fewer agents)
87209	Smear, primary source with interpretation; complex special stain (eg, trichrome, iron hemotoxylin) for ova and parasites
87220	Tissue examination by KOH slide of samples from skin, hair, or nails for fungi or ectoparasite ova or mites (e.g., scabies)
87328	Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple-hyphenstep method; cryptosporidium
87329	giardia
87999	Unlisted microbiology procedure
88199	Unlisted cytopathology procedure
88299	Unlisted cytogenetic study
88399	Unlisted surgical pathology procedure
89125	Fat stains, feces, urine, or respiratory secretions
89160	Meat fibers, feces

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

Code	Code Description
Test and panels that have no specific code(s):	

Kryptopyrrole Test, Great Plains Laboratory's GPL-hyphenTOX Profile (toxic non-hyphenmetal chemicals)

BioHealth:

Other CPT codes related to the CPB:

80053	Comprehensive metabolic panel
80061	Lipid panel
80299	Quantitation of therapeutic drug, not elsewhere specified
82150	Amylase
82172	Apolipoprotein, each
82270	Blood, occult, by peroxidase activity (eg, guaiac), qualitative; feces, consecutive collected specimens with single determination, for colorectal neoplasm screening (ie, patient was provided three cards or single triple card for consecutive collection)
82274	Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-hyphen3 simultaneous determinations
82330	Calcium; ionized
82530	Cortisol; free
82533	Cortisol; total
82550	Creatine kinase (CK), (CPK); total
82607	Cyanocobalamin (Vitamin B-hyphen12)
82627	Dehydroepiandrosterone-hyphensulfate (DHEA-hyphenS)
82670	Estradiol
82677	Estriol
82679	Estrone
82728	Ferritin
82746	Folic acid; serum
82784	Gammaglobulin (immunoglobulin); IgA, IgD, IgG, IgM, each
83090	Homocysteine
83516	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method
83519	Immunoassay, analyte, quantitative; by radiopharmaceutical technique (e.g., RIA)
83527	Insulin; free
83540	Iron
83550	Iron binding capacity
83615	Lactate dehydrogenase (LD), (LDH)
83735	Magnesium
84100	Phosphorus inorganic (phosphate)
84144	Progesterone
84311	Spectrophotometry, analyte not elsewhere specified
84392	Sulfate, urine
84403	Testosterone; total
84436	Thyroxine; total
84439	Thyroxine; free
84443	Thyroid stimulating hormone (TSH)
84466	Transferrin
84481	Triiodothyronine T3; free
84550	Uric acid; blood
84999	Unlisted chemistry procedure

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

Code	Code Description
85018	Blood count; hemoglobin (Hgb)
85025	Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count
85999	Unlisted hematology and coagulation procedure
86141	C-hyphenreactive protein; high sensitivity (hsCRP)
86256	Fluorescent noninfectious agent antibody; titer, each antibody
86430	Rheumatoid factor; qualitative
86628	Antibody; Candida
87081	Culture, presumptive, pathogenic organisms, screening only
87101	Culture, fungi (mold or yeast) isolation, with presumptive identification of isolates; skin, hair, or nail
87106	Culture, fungi, definitive identification, each organism; yeast
87177	Ova and parasites, direct smears, concentration and identification
87324	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-hyphenlinked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-hyphenstep method; Clostridium difficile toxin(s)
87328	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-hyphenlinked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-hyphenstep method; cryptosporidium
87329	giardia
87337	entamoeba histolytica group
87338	helicobacter pylori, stool
87999	Unlisted microbiology procedure
88199	Unlisted cytopathology procedure
88299	Unlisted cytogenetic study
88399	Unlisted surgical pathology procedure

Test and panels that have no specific code(s):

DHEA-hyphens Average, Expanded Circadian Rhythm

DiagnosTechs:

Other CPT codes related to the CPB:

80299	Quantitation of therapeutic drug, not elsewhere specified
84999	Unlisted chemistry procedure
85999	Unlisted hematology and coagulation procedure
87999	Unlisted microbiology procedure
88199	Unlisted cytopathology procedure
88299	Unlisted cytogenetic study
88399	Unlisted surgical pathology procedure

Test and panels that have no specific code(s):

Adrenal Stress Index, Bone Health Panel, Female Hormone Panel, Food Intolerance Panel, Gastrointestinal Health Panel, Male Hormone Panel, Postmenopause and Perimenopause Panels

Doctor's Data Lab:

Other CPT codes related to the CPB:

80299	Quantitation of therapeutic drug, not elsewhere specified
84999	Unlisted chemistry procedure
85999	Unlisted hematology and coagulation procedure

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

Code	Code Description
87999	Unlisted microbiology procedure
88199	Unlisted cytopathology procedure
88299	Unlisted cytogenetic study
88399	Unlisted surgical pathology procedure

Test and panels that have no specific code(s):

Bacteriology Culture, Comprehensive Clostridium Culture, Comprehensive Parasitology, Comprehensive Stool Analysis, Comprehensive Stool Analysis w/Parasitology, Comprehensive Vaginosis Profile, Intestinal Permeability, Lysozyme Stool, Microbiology Profile, Parasitology, Secretory IgA, Stool Chemistry, Stool Yeast Culture, Comprehensive Blood Elements, Fecal Metals, Hair Elements, Hair Toxic Element Exposure Profile, Red Blood Cell (RBC) Elements, Urine Toxic & Essential Elements, Urine Toxic Metals, Whole Blood Chromium & Vanadium, Whole Blood Elements, Comprehensive Drinking Water Analysis, Drinking Water Analysis, DNA Methylation Pathway, Cardiovascular Risk Profile, Comprehensive Cardiovascular Profile, Oxidized LDL, DNA Oxidative Damage Assay, Glutathione, Erythrocytes, Hepatic Detox Profile, Methylation Profile, Urine Porphyrins

ZRT Laboratory:

Other CPT codes related to the CPB:

80299	Quantitation of therapeutic drug, not elsewhere specified
84999	Unlisted chemistry procedure
85999	Unlisted hematology and coagulation procedure
87999	Unlisted microbiology procedure
88199	Unlisted cytopathology procedure
88299	Unlisted cytogenetic study
88399	Unlisted surgical pathology procedure

Test and panels that have no specific code(s):

Weight Management Profile, Fertility Profile, Dried Urine Metabolites, Complete Urine Metabolites, Urine Sex Steroid Metabolites, Urinary Free Cortisols

Aeron Life Cycles:

Other CPT codes related to the CPB:

80299	Quantitation of therapeutic drug, not elsewhere specified
84999	Unlisted chemistry procedure
85999	Unlisted hematology and coagulation procedure
87999	Unlisted microbiology procedure
88199	Unlisted cytopathology procedure
88299	Unlisted cytogenetic study
88399	Unlisted surgical pathology procedure

Test and panels that have no specific code(s):

Saliva Analysis, Urine Bone Marker, BPAssay

Aletess Medical Laboratory:

Other CPT codes related to the CPB:

80299	Quantitation of therapeutic drug, not elsewhere specified
84999	Unlisted chemistry procedure
85999	Unlisted hematology and coagulation procedure

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

Code	Code Description
87999	Unlisted microbiology procedure
88199	Unlisted cytopathology procedure
88299	Unlisted cytogenetic study
88399	Unlisted surgical pathology procedure

Molecular Labs:

Other CPT codes related to the CPB:

83520	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified
86352	Cellular function assay involving stimulation (eg, mitogen or antigen) and detection of biomarker (eg, ATP)
88230	Tissue culture for non-hyphenneoplastic disorders; lymphocyte

Test and panels that have no specific code(s):

Hytex Enzyme Immunoassay, Food Sensitivity Testing Panel, Vegetarian 80 IgG Food Pane, Pediatric 80 IgG Food Panel, Gastrointestinal Panel, Protein Sensitivity Panel, Casein/Gluten Screen, Candida Immune Complex, Candida Profile, Microflora Immune Competency Test, Comprehensive 96 IgG Immune Panel, Comprehensive 184 IgG Immune Panel

Physician Labs:

Other CPT codes related to the CPB:

82175	Arsenic
82300	Cadmium
82533	Cortisol; total
82570	Creatinine; other source
82672	Estrogens; total
82679	Estrone
83018	Heavy metal (eg, arsenic, barium, beryllium, bismuth, antimony, mercury); quantitative, each
83566	Lead
83825	Mercury, quantitative
84403	Testosterone; total

Salveo diagnostic advanced blood/stool testing profiles/panels:

CPT codes not covered for indications listed in the CPB:

Salveo diagnostic advanced blood/stool testing profiles/panels -hyphen No specific code

Dried Urine Test for Comprehensive Hormones (DUTCH) testing:

CPT codes not covered for indications listed in the CPB:

Dried Urine Test for Comprehensive Hormones (DUTCH) testing-hyphen No specific code

Background

Functional medicine is the discipline of healthcare that utilizes laboratory assessment and early intervention to improve physiological, emotional/cognitive, and physical function. This approach focuses attention on biochemical individuality, metabolic balance, ecological context and unique personal experience in the dynamics of health. Evaluating organ "function" versus organ "pathology" is one of the principles of functional medicine. Some manufacturers have developed many laboratory assessment

test panels that purportedly allow physicians to understand a patient's functional status. Using stool, urine, saliva, blood, and hair samples, test panels focus on the functional "status" of the body in 6 areas:

1. digestion (gastrointestinal),
2. nutrition,
3. detoxification/oxidative stress,
4. immunology/allergy,
5. production and regulation of hormones (endocrinology), and/or
6. heart and blood vessels (cardiovascular).

Some manufacturers claim to uncover the root causes of symptoms, allowing the physician to recommend intervention strategies that will solve the chronic problem. Many of these tests employ special substances and protocols to "challenge" organs, supposedly giving the physician an opportunity to evaluate the function of an organ system while it is stressed, thereby providing information that often is missed using conventional laboratory testing. These test panels have been advocated to be of use in the management of patients with various diseases/conditions such as AIDS, Alzheimer's disease, attention deficit/hyperactivity disorder, autism, cardiovascular diseases, chronic fatigue syndrome, cystic fibrosis, depression and mood disorders, headaches, inflammatory bowel disease, insomnia and sleep disorders, male infertility, memory loss and dementia, multiple sclerosis, obesity, osteoarthritis, osteoporosis, premenstrual syndrome, rheumatoid arthritis, sexual dysfunction, and skin disorders.

However, there is no evidence that these laboratory test panels affect the management of afflicted individuals.

PANDAS

A diagnosis of PANDAS is made with prospective evaluation, including documentation, of an episode of neuropsychiatric symptoms associated with evidence of group A streptococcal infection. Diagnostic criteria include obsessive-compulsive disorder and/or tic disorder with a pediatric onset between three years and onset of puberty, abrupt onset and episodic course of symptoms, neurologic abnormalities as well as a temporal relationship between the onset and/or exacerbation of symptoms and a confirmed group A streptococcal infection (Pichichero, 2022). A review by Macerollo et al (2013) stated that "[o]verall, the available evidence does not convincingly support the concept that PANDAS as a well-defined isolated clinical entity subdued by definite pathophysiological mechanisms." The Cunningham Test Panel consists of a series of 5 clinical assays, including the enzyme-linked immunosorbent assays lysogangioside, tubulin, dopamine receptor D1, and dopamine receptor D2 as well as a measure of the level of activity of canclium/calmodulin-dependent protein kinase. Large scale prospectively designed studies are needed to establish an evidence base in support of the Cunningham Test Panel for PANDAS.

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The above policy is based on the following references:

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Policy History

- Last Review 07/12/2024

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Next Review: 05/22/2025

- Review History
- Definitions

Additional Information

- Clinical Policy Bulletin Notes

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