Letter from President Bush – Happy Lab Week dated April 17, 2008

I send greetings to those observing National Medical Laboratory Professionals Week. Across our Nation, medical laboratory professionals are meeting the needs of the sick and bringing hope to patients and their loved ones. National Medical Laboratory Professionals Week is an opportunity to recognize the dedicated men and women who help detect and prevent disease, monitor treatments, and deliver the best care to our citizens. These efforts contribute to a healthier future for our Nation and help save countless lives.

I appreciate the skill and dedication of our Nation's medical laboratory professionals. Your efforts reflect the innovative and compassionate spirit of America.

Laura and I send our best wishes.

George W. Bush

NEW WAIVED TESTS

On October 30, 2007, the Food and Drug Administration (FDA) approved the following under K993211/A002:

- **Abaxis Piccolo xpress Chemistry Analyzer (Comprehensive Metabolic ReagentDisc) {Whole Blood}** and the **Abaxis Piccolo Blood Chemistry Analyzer (Comprehensive Metabolic Reagent Disc) {Whole Blood}** for the analytes alanine aminotransferase (ALT), albumin, alkaline phosphatase, aspartate aminotransferase (AST), total bilirubin, total calcium, creatinine, glucose, total protein, sodium, & urea (BUN) and ;
- **Abaxis Piccolo xpress Chemistry Analyzer (Basic Metabolic Reagent Disc){Whole Blood}**, and the **Abaxis Piccolo Blood Chemistry Analyzer (Basic Metabolic Reagent Disc) {Whole Blood}** for the analytes total calcium, creatinine, glucose, sodium, & BUN and;
- **Abaxis Piccolo xpress Chemistry Analyzer (Electrolyte Reagent Disc) {WholeBlood}** and the **Abaxis Piccolo Blood Chemistry Analyzer (Electrolyte Reagent Disc) {Whole Blood}** for the analyte sodium.

Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On January 22, 2007, the FDA approved the following test systems under K955770/A003 for the analyte gamma glutamyl transferase (GGT):

- **Abaxis Piccolo xpress Chemistry Analyzer,**
- **Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 6 Panel) {Whole Blood}**,
- **Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 6 Panel) {WholeBlood},**
- **Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 13 Panel) {Whole Blood};** and

- **Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 13 Panel) {Whole Blood}.**

Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On January 30, 2008, the FDA approved the **BTNX Inc. Rapid Response Multi-Drug One Step Screen Test Panel (Urine)** and the **BTNX Inc. Know Multi-Drug One Step Screen Test Panel (Urine)**, K063545/A002, for the analytes amphetamines, barbiturates, benzodiazepines, cocaine metabolites, methadone, methamphetamines, morphine, phencyclidine, tricyclic antidepressants, cannabinoids and methylenedioxymethamphetamine. Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On February 13, 2008, the Food and Drug Administration (FDA) approved the **Clarity MONO Mononucleosis Rapid Test {Whole Blood}**, K961024/A006, for the analyte infectious mononucleosis antibodies. Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On February 25, 2008, the FDA approved the **Quidel QuickVue RSV**, K070747/A002, for the analyte respiratory syncytial virus. Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On February 25, 2008, the FDA approved the **Quidel QuickVue RSV**, K061008/A002, for the analyte respiratory syncytial virus. Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On February 26, 2008, the FDA approved the **Henry Schein One Step + Mononucleosis Rapid Test Device {Whole Blood}**, K042272/A020, for the analyte infectious mononucleosis antibodies. Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On February 29, 2008, the FDA approved the **Qualigen, Inc. Fast Chek TSH {Whole Blood}**, K990658/A005, for the analyte thyroid stimulating hormone (TSH). Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On March 4, 2008, the FDA approved the **Henry Schein One Step + Strep A Cassette Test**, K023766/A026, for the analyte group A streptococcus. Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On March 14, 2007, the Food and Drug Administration (FDA) approved the following test systems under K942782/A004:

- **Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 6 Panel) {Whole Blood}** and the **Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 6 Panel) {WholeBlood}**, for the analytes the aspirate aminotransferase (AST), creatinine, glucose and urea (BUN); and
- **Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 13 Panel) {Whole Blood}** and the **Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 13 Panel) {Whole Blood}** for the analytes albumin, AST, total bilirubin, total protein, creatinine, glucose, and urea (BUN).

Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On March 31, 2008, the FDA approved the **Bayer A1CNow + {For professional use}**, K051321/A003, for the analyte glycated hemoglobin, total. Waived status is applicable to the test system and their instructions approved bythe FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On April 8, 2008, the FDA approved the **Diagnostic Test Group Clarity Strep A Rapid Test Strips**, K983386/A009, for the analyte Streptococcus Group A. Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On April 14, 2008, the FDA approved the **Abaxis, Piccolo xpress Chemistry Analyzer (Liver Panel Plus) {Whole Blood}**, K955770/A004, for the analyte gamma glutamyl transferase. Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On April 14, 2008, the FDA approved the **Piccolo Point of Care Chemistry Analyzer (Lipid Panel Plus Reagent Disc) {Whole Blood}**, K023639/A006, for the analyte triglyceride. Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On April 14, 2008, the FDA approved the **Piccolo Point of Care Chemistry Analyzer (Lipid Panel Plus Reagent Disc) {Whole Blood}**, K023640/A006, for the analyte HDL cholesterol. Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On April 14, 2008, the FDA approved the **Abaxis, Piccolo xpress Chemistry Analyzer (Lipid Panel Plus Reagent Disc){Whole Blood}** and the **Abaxis, Piccolo xpress Chemistry Analyzer (Lipid Panel Reagent Disc){Whole Blood}**, K023640/A007, for the analyte HDL cholesterol. Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On April 14, 2008, the FDA approved the **Abaxis, Piccolo xpress Chemistry Analyzer (Lipid Panel Plus Reagent Disc){Whole Blood}** and the **Abaxis, Piccolo xpress Chemistry Analyzer (Lipid Panel Reagent Disc){Whole Blood}**, K023639/A007, for the analyte triglyceride. Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On April 14, 2008, under K950164/A008, the FDA approved the **Abaxis, Piccolo xpress Chemistry Analyzer (Liver Panel Plus){Whole Blood}** for the analytes amylase, alkaline phosphatase (ALP) and alanine aminotransferase (ALT); and the **Abaxis, Piccolo xpress Chemistry Analyzer (Lipid Panel Plus Reagent Disc){Whole Blood}** for the analyte ALT. Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On April 14, 2008, under K942782/A013, the FDA approved the **Abaxis, Piccolo xpress Chemistry Analyzer (Liver Panel Plus){Whole Blood}** for the analytes albumin, aspartate aminotransferase (AST), total bilirubin, and total protein; and the **Abaxis, Piccolo xpress Chemistry Analyzer (Lipid Panel Plus Reagent Disc){Whole Blood}** for the analytes AST and glucose. Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On April 14, 2008, under K023642/A006, the FDA approved the **Abaxis, Piccolo xpress Chemistry Analyzer (Liver Panel Plus Reagent Disc){Whole Blood}**, the **Abaxis, Piccolo xpress Chemistry Analyzer (Liver Panel Reagent Disc){Whole Blood}** and the **Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc){Whole Blood}**, for the analyte cholesterol. Waived status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.