

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

## Indications for Use

510(k) Number (*if known*)  
K181412

Device Name  
VITEK® MS

Indications for Use (*Describe*)

VITEK® MS is a mass spectrometry system using matrix-assisted laser desorption/ionization time of flight mass spectrometry (MALDI-TOF MS) for the identification of microorganisms cultured from human specimens.

The VITEK® MS system is a qualitative in vitro diagnostic device indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial, yeast and mould infections.

(See Attached for 'List of Claimed Organisms')

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**Section 1.5 (Continued)****Indications for Use Attachment****Gram Negative / Positive  
Bacteria & Yeast**

*Abiotrophia defectiva*  
*Achromobacter denitrificans*  
*Achromobacter xylosoxidans*  
*Acinetobacter baumannii*  
*Acinetobacter calcoaceticus*  
*Acinetobacter haemolyticus*  
*Acinetobacter johnsonii*  
*Acinetobacter junii*  
*Acinetobacter lwoffii*  
*Acinetobacter nosocomialis*  
*Acinetobacter pittii*  
*Actinomyces bovis*  
*Actinomyces israelii*  
*Actinomyces meyeri*  
*Actinomyces naeslundii*  
*Actinomyces neuui*  
*Actinomyces odontolyticus*  
*Actinotignum schaalii*  
*Aerococcus viridans*  
*Aeromonas hydrophila*  
*Aeromonas jandaei*  
*Aeromonas punctata (caviae)*  
*Aeromonas sobria*  
*Aggregatibacter actinomycetemcomitans*  
*Aggregatibacter aphrophilus*  
*Aggregatibacter segnis*  
*Alcaligenes faecalis ssp faecalis*  
*Bacteroides caccae*  
*Bacteroides eggerthii*  
*Bacteroides fragilis*  
*Bacteroides ovatus / xylanisolvens*  
*Bacteroides pyogenes*  
*Bacteroides stercoris*  
*Bacteroides thetaiotaomicron*  
*Bacteroides uniformis*  
*Bacteroides vulgatus*  
*Bifidobacterium spp*  
*Bilophila wadsworthia*  
*Bordetella avium*  
*Bordetella bronchiseptica*  
*Bordetella parapertussis*  
*Bordetella pertussis*  
*Brevundimonas diminuta*  
*Brevundimonas vesicularis*  
*Brucella spp*  
*Burkholderia cenocepacia*  
*Burkholderia cepacia*  
*Burkholderia contaminans*  
*Burkholderia gladioli*  
*Burkholderia multivorans*  
*Burkholderia vietnamiensis*  
*Campylobacter coli*  
*Campylobacter jejuni*  
*Campylobacter rectus*  
*Candida albicans*  
*Candida auris*  
*Candida dubliniensis*  
*Candida duobushaemulonii*  
*Candida famata*  
*Candida glabrata*  
*Candida guilliermondii*  
*Candida haemulonii*  
*Candida inconspicua*  
*Candida intermedia*  
*Candida kefyr*  
*Candida krusei*  
*Candida lambica*  
*Candida lipolytica*  
*Candida lusitanae*  
*Candida metapsilosis*  
*Candida norvegensis*  
*Candida orthopsilosis*  
*Candida parapsilosis*  
*Candida pelliculosa*  
*Candida rugosa*  
*Candida tropicalis*  
*Candida utilis*  
*Candida zeylanoides*  
*Cedecea davisae*  
*Cedecea lapagei*  
*Cedecea neteri*  
*Chryseobacterium gleum*  
*Chryseobacterium indologenes*  
*Citrobacter amalonaticus*  
*Citrobacter braakii*  
*Citrobacter farmeri*  
*Citrobacter freundii*  
*Citrobacter koseri*  
*Citrobacter youngae*  
*Clostridium baratii*  
*Clostridium beijerinckii*  
*Clostridium butyricum*  
*Clostridium cadaveris*

**Section 1.5 (Continued)**

*Clostridium clostridioforme*  
*Clostridium difficile*  
*Clostridium innocuum*  
*Clostridium novyi*  
*Clostridium perfringens*  
*Clostridium ramosum*  
*Clostridium septicum*  
*Clostridium sporogenes*  
*Clostridium tertium*  
*Clostridium tetani*  
*Comamonas testosteroni*  
*Corynebacterium jeikeium*  
*Cronobacter muytjensii*  
*Cronobacter sakazakii*  
*Cronobacter turicensis*  
*Cryptococcus gattii*  
*Cryptococcus neoformans*  
*Curtobacterium flaccumfaciens*  
*Delftia acidovorans*  
*Edwardsiella hoshinae*  
*Edwardsiella tarda*  
*Eikenella corrodens*  
*Elizabethkingia anophelis*  
*Elizabethkingia meningoseptica*  
*Elizabethkingia miricola*  
*Enterobacter aerogenes*  
*Enterobacter asburiae*  
*Enterobacter cancerogenus*  
*Enterobacter cloacae*  
*Enterobacter hormaechei*  
*Enterobacter kobei*  
*Enterobacter ludwigii*  
*Enterococcus avium*  
*Enterococcus casseliflavus*  
*Enterococcus durans*  
*Enterococcus faecalis*  
*Enterococcus faecium*  
*Enterococcus gallinarum*  
*Enterococcus hirae*  
*Escherichia coli*  
*Escherichia fergusonii*  
*Escherichia hermannii*  
*Escherichia vulneris*  
*Ewingella americana*  
*Finegoldia magna*  
*Fusobacterium mortiferum*  
*Fusobacterium necrophorum*  
*Fusobacterium nucleatum*  
*Fusobacterium periodonticum*  
*Gardnerella vaginalis*  
*Gemella haemolysans*  
*Gemella morbillorum*  
*Granulicatella adiacens*  
*Haemophilus influenzae*  
*Haemophilus parahaemolyticus*  
*Haemophilus parainfluenzae*  
*Hafnia alvei*  
*Hathewayia histolytica*  
*Kingella denitrificans*  
*Kingella kingae*  
*Klebsiella oxytoca*  
*Klebsiella pneumoniae*  
*Klebsiella variicola*  
*Kluyvera ascorbata*  
*Kluyvera cryocrescens*  
*Kluyvera intermedia*  
*Kocuria rhizophila*  
*Kodamaea ohmeri*  
*Lactococcus garvieae*  
*Lactococcus lactis*  
*Leclercia adecarboxylata*  
*Legionella pneumophila*  
*Lelliottia amnigena*  
*Leuconostoc mesenteroides*  
*Leuconostoc pseudomesenteroides*  
*Listeria monocytogenes*  
*Malassezia furfur*  
*Malassezia pachydermatis*  
*Mannheimia haemolytica*  
*Micrococcus luteus*  
*Mobiluncus curtisii*  
*Moraxella catarrhalis*  
*Moraxella lacunata*  
*Moraxella nonliquefaciens*  
*Moraxella osloensis*  
*Morganella morganii*  
*Myroides spp*  
*Neisseria cinerea*  
*Neisseria gonorrhoeae*  
*Neisseria meningitidis*  
*Neisseria mucosa / sicca*  
*Ochrobactrum anthropi*  
*Oligella ureolytica*  
*Oligella urethralis*  
*Paeniclostridium sordellii*  
*Pantoea agglomerans*  
*Pantoea dispersa*

**Section 1.5 (Continued)**

*Paraclostridium bifermentans*  
*Parvimonas micra*  
*Pasteurella aerogenes*  
*Pasteurella multocida*  
*Pediococcus acidilactici*  
*Peptoniphilus asaccharolyticus*  
*Peptostreptococcus anaerobius*  
*Plesiomonas shigelloides*  
*Pluralibacter gergoviae*  
*Porphyromonas asaccharolytica / uenonis*  
*Porphyromonas gingivalis*  
*Prevotella bivia*  
*Prevotella buccae*  
*Prevotella denticola*  
*Prevotella intermedia*  
*Prevotella loescheii*  
*Prevotella melaninogenica*  
*Prevotella oralis*  
*Prevotella oris*  
*Propionibacterium acidipropionici*  
*Propionibacterium acnes*  
*Propionibacterium avidum*  
*Propionibacterium granulosum*  
*Propionibacterium propionicum*  
*Proteus mirabilis*  
*Proteus penneri*  
*Proteus vulgaris*  
*Providencia alcalifaciens*  
*Providencia rettgeri*  
*Providencia rustigianii*  
*Providencia stuartii*  
*Pseudomonas aeruginosa*  
*Pseudomonas alcaligenes*  
*Pseudomonas fluorescens*  
*Pseudomonas luteola*  
*Pseudomonas mendocina*  
*Pseudomonas oryzihabitans*  
*Pseudomonas putida*  
*Pseudomonas stutzeri*  
*Ralstonia pickettii*  
*Raoultella ornithinolytica*  
*Raoultella planticola*  
*Raoultella terrigena*  
*Rhizobium radiobacter*  
*Rhodotorula mucilaginosa*  
*Rothia mucilaginosa*  
*Saccharomyces cerevisiae*  
*Salmonella enterica ssp enterica*  
*Saprochaete capitata*  
*Serratia ficaria*  
*Serratia fonticola*  
*Serratia grimesii*  
*Serratia liquefaciens*  
*Serratia marcescens*  
*Serratia odorifera*  
*Serratia plymuthica*  
*Serratia proteamaculans*  
*Serratia quinivorans*  
*Serratia rubidaea*  
*Shewanella putrefaciens*  
*Sphingobacterium multivorum*  
*Sphingobacterium spiritivorum*  
*Sphingomonas paucimobilis*  
*Staphylococcus aureus*  
*Staphylococcus auricularis*  
*Staphylococcus capitis*  
*Staphylococcus chromogenes*  
*Staphylococcus cohnii ssp cohnii*  
*Staphylococcus cohnii ssp urealyticus*  
*Staphylococcus epidermidis*  
*Staphylococcus haemolyticus*  
*Staphylococcus hominis*  
*Staphylococcus hyicus*  
*Staphylococcus intermedius*  
*Staphylococcus kloosii*  
*Staphylococcus lentus*  
*Staphylococcus lugdunensis*  
*Staphylococcus pseudintermedius*  
*Staphylococcus saprophyticus*  
*Staphylococcus schleiferi*  
*Staphylococcus sciuri*  
*Staphylococcus simulans*  
*Staphylococcus warneri*  
*Staphylococcus xylosum*  
*Stenotrophomonas maltophilia*  
*Streptococcus agalactiae*  
*Streptococcus alactolyticus*  
*Streptococcus anginosus*  
*Streptococcus canis*  
*Streptococcus constellatus*  
*Streptococcus cristatus*  
*Streptococcus dysgalactiae ssp dysgalactiae*  
*Streptococcus dysgalactiae ssp equisimilis*  
*Streptococcus equi ssp equi*  
*Streptococcus equi ssp zooepidemicus*  
*Streptococcus equinus*  
*Streptococcus gallolyticus ssp gallolyticus*  
*Streptococcus gallolyticus ssp pasteurianus*  
*Streptococcus gordonii*

**Section 1.5 (Continued)**

*Streptococcus infantarius* ssp *coli* (*Str.lutetiensis*)  
*Streptococcus infantarius* ssp *infantarius*  
*Streptococcus intermedius*  
*Streptococcus mitis* / *Streptococcus oralis*  
*Streptococcus mutans*  
*Streptococcus parasanguinis*  
*Streptococcus pneumoniae*  
*Streptococcus pseudoporcinus*  
*Streptococcus pyogenes*  
*Streptococcus salivarius* ssp *salivarius*  
*Streptococcus sanguinis*  
*Streptococcus sobrinus*  
*Streptococcus suis*  
*Streptococcus uberis*  
*Streptococcus*  
*vestibularis*  
*Tannerella forsythia*  
*Veillonella dispar*  
*Vibrio alginolyticus*  
*Vibrio cholerae*  
*Vibrio fluvialis*  
*Vibrio metschnikovii*  
*Vibrio mimicus*  
*Vibrio parahaemolyticus*  
*Vibrio vulnificus*  
*Yersinia aldovae*  
*Yersinia enterocolitica*  
*Yersinia frederiksenii*  
*Yersinia intermedia*  
*Yersinia kristensenii*  
*Yersinia pseudotuberculosis*  
*Yersinia ruckeri*

**Mycobacterium**

*Mycobacterium abscessus*  
*Mycobacterium avium*  
*Mycobacterium chelonae*  
*Mycobacterium fortuitum* group  
*Mycobacterium gordonae*  
*Mycobacterium haemophilum*  
*Mycobacterium immunogenum*  
*Mycobacterium intracellulare*  
*Mycobacterium kansasii*  
*Mycobacterium lentiflavum*  
*Mycobacterium malmoense*  
*Mycobacterium marinum*  
*Mycobacterium mucogenicum*  
*Mycobacterium scrofulaceum*  
*Mycobacterium simiae*

*Mycobacterium smegmatis*  
*Mycobacterium szulgai*  
*Mycobacterium tuberculosis* complex  
*Mycobacterium xenopi*

**Nocardia**

*Nocardia abscessus*  
*Nocardia africana* / *nova*  
*Nocardia asteroides*  
*Nocardia brasiliensis*  
*Nocardia cyriacigeorgica*  
*Nocardia farcinica*  
*Nocardia otitidiscaviarum*  
*Nocardia paucivorans*  
*Nocardia pseudobrasiliensis*  
*Nocardia transvalensis*  
*Nocardia veterana*  
*Nocardia wallacei*

**Mould**

*Acremonium sclerotigenum*  
*Alternaria alternata*  
*Aspergillus brasiliensis*  
*Aspergillus calidoustus* / *ustus*  
*Aspergillus flavus* / *oryzae*  
*Aspergillus fumigatus*  
*Aspergillus lentulus*  
*Aspergillus nidulans*  
*Aspergillus niger* complex  
*Aspergillus sydowii*  
*Aspergillus terreus* complex  
*Aspergillus versicolor*  
*Blastomyces dermatitidis*  
*Cladophialophora bantiana*  
*Coccidioides immitis* / *posadasii*  
*Curvularia hawaiiensis*  
*Curvularia spicifera*  
*Epidermophyton floccosum*  
*Exophiala dermatitidis*  
*Exophiala xenobiotica*  
*Exserohilum rostratum*  
*Fusarium oxysporum* complex  
*Fusarium proliferatum*  
*Fusarium solani* complex  
*Histoplasma capsulatum*  
*Lecythophora hoffmannii*  
*Lichtheimia corymbifera*  
*Microsporium audouinii*

**Section 1.5 (Continued)**

*Microsporum canis*  
*Microsporum gypseum*  
*Mucor racemosus* complex  
*Paecilomyces variotii* complex  
*Penicillium chrysogenum*  
*Pseudallescheria boydii*  
*Purpureocillium lilacinum*  
*Rasamsonia argillacea* complex  
*Rhizopus arrhizus* complex  
*Rhizopus microsporus* complex  
*Sarocladium kiliense*  
*Scedosporium apiospermum*

*Scedosporium prolificans*  
*Sporothrix schenckii* complex  
*Trichophyton interdigitale*  
*Trichophyton rubrum*  
*Trichophyton tonsurans*  
*Trichophyton verrucosum*  
*Trichophyton violaceum*  
*Trichosporon asahii*  
*Trichosporon dermatis / mucoides*  
*Trichosporon inkin*