

MMQC-11-1341 \ IMMEDIATE MSG / BIOMERIEUX, INC / VITEK 2 GRAM NEGATIVE
SUSCEPTIBILITY CARDS CONTAINING PIPERACILLIN/TAZOBACTAM (TZP) -
EXPANDED RECALL / FDA CLASS I RECALL / DLA 11-179

FROM
QUAD SERVICE MMQC FT DETRICK MD//USAMMA/AFMLO/NMLC//

IMMEDIATEMESSAGE RELEASED: 05/05/2011

*****UNCLASSIFIED*****

SUBJ: MMQC-11-1341
IMMEDIATE MSG / BIOMERIEUX, INC / VITEK 2 GRAM NEGATIVE SUSCEPTIBILITY
CARDS CONTAINING PIPERACILLIN/TAZOBACTAM (TZP) - EXPANDED RECALL / FDA
CLASS I RECALL / DLA 11-179

REF: MMQC-10-1684

ACTIVITIES MUST ACKNOWLEDGE RECEIPT OF THIS MSG; SEE PARA 05.

SUSPENSE: 5/10/2011

01. FDA CLASS I RECALL ON FOL MATL. REASON: PIPERACILLIN/TAZOBACTAM
ANTIBIOTIC ON ANTIMICROBIAL SUSCEPTIBILITY CARDS IS PROVIDING FALSE
SUSCEPTIBLE & FALSE RESISTANT RESULTS FOR E. COLI & SEVEN ADDITIONAL
ORGANISMS, PSEUDOMONAS AERUGINOSA, SALMONELLA ENTERICA, PROVIDENCIA
STUARTII, PROVIDENCIA RETTGERI, PROTEUS VULGARIS, PROTEUS MIRABILIS, &
MORGANELLA MORGANII (SEE PARA 03). DISP: COMPLY W/MFR/DIST INSTRS IF
RECD.

ON 4 APRIL 2011, COMPANY SENT ITS CUSTOMERS A NOTICE (SEE PARA 04).
QUESTIONS, CALL 800-682-2666, OPTION 3 OR 919-620-2000.

NSN: 6550-NS1 UI: EA
NOM: VITEK 2 GRAM NEGATIVE SUSCEPTIBILITY CARDS; AST-N183,REF 411021
MFR: BIOMERIEUX, INC
LOT/SERIAL NUMBER(S):
ALL

02. REASON AND DISPOSITION AS ABOVE.

NSN: 6550-NS2 UI: EA
NOM: VITEK 2 GRAM NEGATIVE SUSCEPTIBILITY CARDS; AST-N184,REF 411154

MFR: BIOMERIEUX, INC
LOT/SERIAL NUMBER(S):
ALL

NOTE 1: ABOVE PRODUCTS (UNDER THE EXPANDED RECALL) WERE DISTRIBUTED IN FOREIGN COUNTRIES ONLY.

NOTE 2: PRODUCT DISTRIBUTED FROM SEPTEMBER 2010 THROUGH APRIL 2011.

03. THE SAME ANTIBIOTIC IS PROVIDING FALSE RESISTANT RESULTS FOR KLEBSIELLA PNEUMONIAE. INCORRECT RESULTS COULD POTENTIALLY LEAD TO PATIENTS BEING INAPPROPRIATELY TREATED WITH PIPERACILLIN/TAZOBACTAM, WHICH COULD CAUSE SERIOUS INJURY OR DEATH.

04. "URGENT PRODUCT CORRECTION NOTICE VITEK 2 PIPERACILLIN/TAZOBACTAM TEST," INFORMING ITS CUSTOMERS OF THE REASON FOR THE RECALL AND INCLUDES THE EXPANSION OF THE ADDITIONAL ORGANISM. CUSTOMERS ARE TO PERFORM THE FOLLOWING TWO ACTIONS WHEN USING PIPERACILLIN/TAZOBACTAM (TZP) IN TESTING.

-- USE AN ALTERNATIVE METHOD FOR TESTING AND REPORTING OF PIPERACILLIN/TAZOBACTAM SUSCEPTIBILITY FOR MORGANELLA MORGANII, PROTEUS MIRABILIS, PROTEUS VULGARIS, PROVIDENCIA RETTGERI, PROVIDENCIA STUARTII, PSEUDOMONAS AERUGINOSA, SALMONELLA ENTERICA, E.COLI AND KLEBSIELLA PNEUMONIAE WITH RESISTANT PIPERACILLIN/TAZOBACTAM RESULTS; AND

-- CONFIGURE THE VITEK 2 SOFTWARE TO SUPPRESS TZP RESULTS FROM REPORTING.

THE INSTRUCTIONS CONTAINED IN THE RECALL NOTICE ARE TO BE APPLIED TO ALL CURRENT AND FUTURE PRODUCT LOTS THAT CONTAIN TZP UNTIL FURTHER NOTICE.

IN ADDITION TO THE NOTICE, A MULTI-LANGUAGE INSERT WILL GO INTO BOXES OF FUTURE SHIPMENTS TO THE CUSTOMERS THAT REMIND THEM OF THE ACTIONS THEY MUST TAKE REGARDING TZP. THE RECALL NOTIFICATION WILL ACCOMPANY ALL SHIPMENTS OF INSTRUMENT SOFTWARE KITS FOR NEW CUSTOMERS.

05. CONUS AND OCONUS ACTIVITIES WILL ACKNOWLEDGE RECEIPT OF THIS

MESSAGE NLT

10 MAY 2011, VIA USAMMA WEBPAGE AT: [HTTP://WWW.USAMMA.ARMY.MIL](http://www.usamma.army.mil) SELECT "PRODUCTS," SELECT "DOD MEDICAL MATERIEL QUALITY CONTROL MESSAGES (MMQC) & IMAGES," THEN SELECT "DOD IMMEDIATE MMQC MESSAGE RECEIPT ACKNOWLEDGEMENT." THE DIRECT LINK IS [HTTP://WWW.USAMMA.ARMY.MIL/ASSETS/APPS/NALA_QAWEB/MMQC_ACK_SERVICE.CFM](http://www.usamma.army.mil/assets/apps/nala_qaweb/mmqc_ack_service.cfm) THE RESPONDER NEEDS TO SELECT THE APPROPRIATE SERVICE AND FILL IN THE APPROPRIATE INFORMATION. UPON SUBMITTING THIS INFORMATION IT IS THEN ELECTRONICALLY FORWARDED TO THE APPROPRIATE SERVICE REPRESENTATIVE.

06. PASS MSG TO MEDICAL LOG OFCRS, CMD CHANNELS, MED STAFF, LAB, SUPPLY OFCRS, AND SUPPORTED ACTYS/CTRS.

07. AUTHORITY: DODD 5105.22 AND DODD 6025.13. ADDITIONALLY:

A. ARMY: SEE ARMY REGULATION (AR) 40-61, 28 JANUARY 2005, CHAPTER 4, AND THE DEPARTMENT OF THE ARMY SUPPLY BULLETIN (SB 8-75-11) FOR APPLICABLE POLICIES AND PROCEDURES.

B. AIR FORCE: AF ACTIVITIES WILL TAKE ACTION AS PRESCRIBED IN AFI 41-209, MEDICAL LOGISTICS SUPPORT, CHAPTERS 3 AND 9. FOR MAJCOMS & NGB--THIS MSG HAS BEEN TRANSMITTED TO ALL DESIGNATED SUBORDINATE MEDICAL ACTIVITIES.

08. SERVICE SPECIFIC POCS ARE AS FOLS (FAX NOS. ARE AVAILABLE 24 HRS);

ARMY: TELEPHONE COM: 301-619-3242, DSN: 343, FAX: 4468,
E-MAIL: QUADSERVICEMMQC@AMEDD.ARMY.MIL

ARMY MEMBERS MAY SUBSCRIBE TO DOD MMQC MESSAGES AND MANY OTHER TOPICS AT THE FOLLOWING WEBSITE:
[HTTP://WWW.USAMMA.ARMY.MIL/ASSETS/APPS/NALA_QAWEB/NALA_INDEX.CFM](http://www.usamma.army.mil/assets/apps/nala_qaweb/nala_index.cfm)
CLICK ON "SUBSCRIBE TO MMQC MESSAGES HERE."

USAMMC-E: TELEPHONE COM: 011-49-6331-86-7118/7181, DSN: 495-7118, FAX: 6218,
E-MAIL: USAMMCE_QA@AMEDD.ARMY.MIL

AIR FORCE: TELEPHONE COM: 301-619-4170, DSN: 343, FAX: 2557
EMAIL: AFMOA.SGALC@DETRICK.AF.MIL

AIR FORCE MEMBERS MAY SUBSCRIBE TO THE DOD MMQC MESSAGES AND RECEIVE EMAIL

NOTIFICATIONS DIRECTLY FROM USAMMA WHEN THEY ARE PUBLISHED AT THE FOL
WEBSITE:

[HTTPS://MEDLOG.DETRICK.AF.MIL/](https://medlog.detrick.af.mil/), GO TO "SITE SETTINGS" AND CHECK
"SUBSCRIBE TO MMQC
MESSAGES."

NAVY: TELEPHONE COM: 301-619-3085, DSN: 343, FAX: 3087,
EMAIL: MMQC2@MED.NAVY.MIL

NAVY MEMBERS MAY SUBSCRIBE TO RECEIVE DODMMQC MESSAGES AT
[HTTP://WWW.USAMMA.ARMY.MIL](http://www.usamma.army.mil)
CLICK ON "SUBSCRIBE TO MMQC MESSAGES."