QUALITY CONTROL MANUAL

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MAINTENANCE OF ISOLATES FOR QUALITY CONTROL

STOCK CULTURES

Reference strains for quality control are originally obtained from ATCC, Microbiologicals or other commercial sources as lyophilised cultures. Follow manufacturer's instructions and subculture these lyophilised cultures. Store the subcultured isolates in trisodium citrate glycerol at -70° C. These frozen cultures are used as STOCK CULTURES and should be replaced annually.
Viruses are kept in DMSO in liquid nitrogen.

WORKING CULTURES

Working cultures are stored on TSB agar slants at 4° to 8°C or on Chocolate agar or Blood Agar for fastidious organism. These cultures are replaced monthly by subculturing from the Stock Cultures.
Virus working cultures are propagated in the appropriate tube culture cell lines.

BEFORE TESTING

Before testing, cultures are subcultured from the working cultures onto solid media before use.
Not applicable for viruses

QUALITY CONTROL OF CULTURE MEDIA

PROCEDURE FOR QC ON COMMERCIALLY PREPARED MEDIA:

All prepared media received will be examined visually for colour change, precipitate, lysis of blood, contamination etc. Any atypical observation should be brought to the attention of the QA technologist. An incident report form will then be filled out and faxed to the supplier.

Performance quality control testing for routine media supplied by OXOID/MEDPRED, PML or QUELAB is not required except the following:

Skirrow's Campylobacter agar	Bile Esculin agar
Chocolate agar	Bile Esculin slant
Enterococcus Vancomycin agar	MOP broth
Haemophilus isolation agar	TSI slant
Mannitol Salt agar with 4 µg/ml oxacillin	Urea slant
Martin-Lewis agar	Todd Hewitt broth
Oxacillin screen plate	Mueller Hinton agar
Sorbitol-MacConkey agar	Inhibitory mould agar
High-Level Aminoglycoside/Vancomycin resistant screen plate (QUAD)	Kanamycin/Vancomycin agar

On receipt of these media, a sufficient amount of each lot will be set aside for performance testing. Register each item into the "micqc" module of the LIS.

QC Organism Preparation, Inoculation and Reading

For all isolates except *N. gonorrhoeae, H. influenzae* and *C.jejuni*:

Prepare a saline suspension of all required isolates to a turbidity to match 0.5 McFarland standard. Inoculate media using a calibrated 1 uL (0.001 mL) loop. Incubate as required and inspect cultures at 24 and 48 hours. Record as "OK" in the LIS or if not acceptable, enter this into the "Result Comment" field in the LIS, fill out an incident form, inform the supplier and remove media from the refrigerator shelf.

For *N. gonorrhoeae, H. influenzae* and *C.jejuni*:

Prepare a saline suspension of the isolates to a turbidity to match 0.5 McFarland standard. Make a 1:10 dilution of those suspensions and inoculate from the diluted suspensions onto the agar plates using a calibrated 1 uL (0.001 mL) loop. Incubate as required and inspect cultures at 24 and 48 hours. Record as "OK" in the LIS or if not acceptable, enter this into the "Result Comment" field in the LIS, fill out an incident form, inform the supplier and remove media from the refrigerator shelf.

ORGANISMS FOR MEDIA QC

MEDIA	ORGANISMS	EXPECTED RESULTS
Oxacillin screen plate	*S. aureus* LPTP 8610	Growth
	S. aureus ATCC 43300	Growth
	S. aureus ATCC 29213	No growth
	S. aureus ATCC 43387	No growth
Campylobacter agar	*Campylobacter jejuni* ATCC 29428	Growth
	E. coli ATCC 25922	No growth
Chocolate agar	*N. gonorrhoeae* ATCC 43069*	Growth
	H. influenzae ATCC 10211*	Growth
Enterococcus Vancomycin agar	*E. facealis* ATCC 51299	Growth
	E. gallinarum ATCC 35038	Growth
	E. facealis ATCC 29212	No growth
	E. coli ATCC 25922	No growth

MEDIA	**ORGANISMS**	**EXPECTED RESULTS**
Haemophilus isolation agar	*S. aureus* ATCC 29213	No growth
	H. influenzae ATCC 10211*	Growth
Mannitol Salt agar with Oxacillin	*S. epidermidis* ATCC 12228	No growth
	S. aureus ATCC 43300	Yellow colonies
	S. aureus ATCC 29213	No growth
	S. aureus LPTP 8610	Yellow colonies
	E coli ATCC 25922	No growth
Martin-Lewis agar	*N. gonorrhoeae* ATCC 43069*	Growth
	P. mirabilis ATCC 12453	No growth
	S. epidermidis ATCC 12228	No growth
Mueller Hinton agar with Gentamicin 10µg disc	*P. aeruginosa* ATCC 27853	16-21 mm zone
Mueller Hinton agar with TMP/SMX disc	*E. faecalis* ATCC 29212	≥20 mm zone

MEDIA	**ORGANISMS**	**EXPECTED RESULTS**
QUAD	*E. faecalis*	Gent-Growth
	ATCC 49532	Strep-No growth
		Vanc-No growth
	E. faecalis	Gent-No growth
	ATCC 49533	Strep-Growth
		Vanc-No growth
	E. gallinarum	Gent-No growth
	ATCC 35038	Strep-No Growth
		Vanc-Growth
Sorbitol-MacConkey agar	*E. coli* ATCC 25922	Pink colonies
	E. coli O157:H7	Colourless colonies
	LPTP 8608-3	
OCBL	*Burkholderia cepacia*	Growth –Yellow
	ATCC 25608	
	P. aerugionosa ATCC 27853	Growth -Not yellow
TCBS	*Vibrio aglinolyticus*	Growth-Yellow
	ATCC 17749	
	E. coli ATCC 25922	No growth
MCPOD (MacConkey agar with 2 µg/ml cefpodoxime)	*K. pneumoniae* ATCC 13883	No growth
	K. pneumoniae CAP 98D-A	Growth
Inhibitory Mould agar	*T. mentagrophytes*	Growth
	ATCC 9533	

MEDIA	**ORGANISMS**	**EXPECTED RESULTS**
Kanamycin / Vancomycin agar	*B. fragilis* ATCC 25285	Growth
	E. coli ATCC 25922	No growth
Todd-Hewitt broth with genta	*S. agalactiae* ATCC 13813	Growth
	S. aureus ATCC 29213	Growth
	E. coli ATCC 25922	No growth

* Use the 1:10 dilution of the 0.5 McFarland suspension for inoculation.

PROCEDURE FOR QC ON MEDIA PREPARED IN-HOUSE:

Visual inspection includes observing the media for color change, precipitate, lysis of blood, etc. Any atypical observation should be brought to the attention of the QA technologist. If the medium is visually satisfactory, write "OK" in the space provided.

pH testing will be performed on the final medium after it has solidified and cooled to room temperature. Record the value obtained.

For blood that has been added to freshly prepared agar, one drop is put onto BA and incubated at 35°C for 48 hours and then at RT for a further 48 hours.

Sterility testing will be performed on all media prepared in our laboratory. One plate or tube from each batch will be incubated at 35° C for 48 hours, one at RT for 48 hours, and a third is refrigerated for 7 days, then incubated at 35° C for 48 hours.

Performance testing will be done using the Standard Loop method. One plate from each batch will be tested when first prepared and again on each successive 7 days until the supply in the refrigerator is depleted or the expiry date is reached. If expected results are not attained, the QA technologist must be informed.

SHEEP/HORSE BLOOD STERILITY TESTING

Initial Testing (performed at the Blood Culture bench)

On receipt in the laboratory, each bottle is assigned a letter (A, B, C, etc.). The type of blood, lot #, expiry date, and hematocrit (found on label of bottle) is entered into the LIS and BacT/Alert in the following manner:

i. Enter the vial location.

ii. Enter the accession # as bottle letter (space) hematocrit.
eg. A 39, B 40, C 39, etc.

iii. Enter the name as follows: type of blood, lot #, expiry date.
eg. sheep 130820 112387, horse 130825 112387, etc
As for routine patient specimens, </> will bring up the information entered for the previous specimen.

With a needle and syringe 2.5 mL of blood is aseptically removed from each bottle of blood and inoculated into separate BacT/Alert FAN aerobic bottles. The original bottles of blood are immediately refrigerated and the BacT/Alert bottles are incubated in the BacT/Alert incubator and processed as routine specimens.

Print-out of LIS results will be filed with the invoice on QA bench. If any bottle gives a positive reading, the QA technologist must be informed as soon as possible and the original bottle of blood is removed from use. The BacT/Alert bottle is Gram stained and subcultured to BA (AnO_2) and CHOC (CO_2). Identification to the species level (eg. Staphylococcus, diphtheroid, etc) will be sufficient.

After Use (performed by media preparation and the QA technologist.

As each bottle of blood is used, the last few drops of blood are inoculated onto a BA plate which is labelled with the lot # and letter. This plate is incubated at 35°C for 48 hours, then at RT for 48 hours. The results are recorded as a QC item in the LIS for the medium that the blood has been added to.

VITEK QUALITY CONTROL

Follow schedule generated from LIS for frequency of QC.

QC all new lots of **identification cards** once when received in the lab. No further QC is required if all results are within limits. Perform QCs for 5 consecutive days if out-of-control results are observed (see QA technologist).

QC all new lots of **susceptibility cards** once when received and once weekly when lot is in used. Perform daily QCs when any out-of-
control results are observed (see QA technologist).

QUALITY CONTROL SET UP FOR VITEK BENCH

DAY 1

Subculture purity plates from the stock slants to BA for the next days QC requirements.

DAY 2

1. Remove fresh subculture plates from incubator and check for purity.

2. At Main Menu:
   a. click "**VITEK**"
   b. click "**QC**"
   c. click "**LOADLIST**"
   d. select card by scrolling screen by screen; hi-light appropriate card type and lot # by holding left button down
   e. click "**PRINT**"
   f. click "**SELECTED ITEM**"

3. Proceed to set up cards according to the load list.

DAY 3:

1. Remove purity plates from incubator and check purity.

2. Upon completion of the test, results will be transferred automatically to the permanent QC data base.

3. Go to QC file to check for errors:
   a. click on "**VITEK**"
   b. click on "**QC**"
   c. click on "**VIEW RESULTS**"
   d. enter: **test type**
      lot #
      date range
      deviations only
      click "**OK**"
   e. if exceptions are present, click "**YES**" to load results
   f. click "**PRINT**"
   g. click "¨ " if there are more than one exceptions for this card type.
   h. click "**FILE**"
   i. click "**QUIT**"
   j. click "**SYSTEM**"
   k. move cursor to the problem QC card and click
   l. click "**LAB REPORT**" button, hold left button and move cursor to "**RAW DATA REPORT**"
   m. click "**PRINT**"
   n. See Pauline/Glen for corrective action.
   o. File load list, exception list, QC exception reports and raw data printouts in QC binder.
   p. Repeat steps b to o for all card types.

   For QC Results that appear in the "REVIEW" file eg. unidentified organism, delete result and repeat test.

KIRBY BAUER QUALITY CONTROL

A. CONTROL STRAINS

1. To control the precision and accuracy of the test procedure, the following organisms are to be maintained:

Staphylococcus aureus	ATCC 25923
Escherichia coli	ATCC 25922
Pseudomonas aeruginosa	ATCC 27853
Haemophilus influenzae	ATCC 49247
Enterococcus faecalis	ATCC 29212

2. Working cultures are stored on TSB agar slants at 4^{o} to 8^{o}C (Chocolate agar for *H. influenzae*). Stock cultures are stored in trisodium citrate glycerol at -70^{o} C.

3. Before testing cultures are subcultured from the working culture slants (*Haemophilus* is subcultured on alternate days).

4. Replace working cultures monthly from frozen stock cultures.

5. For testing, inoculate the culture into broth, incubate 4 to 18 hours, then streak onto Blood agar or Chocolate agar to obtain single colonies.

6. Choose colonies for testing according to the recommended procedures.

7. Continue to use these cultures as long as there is no significant change in the mean zone diameter that cannot be attributed to methodology. Obtain fresh cultures from the ATCC or any reliable commercial source.

B. ANTIBIOTICS TO BE TESTED

1. Test the control organisms using the antimicrobial discs which are used to test clinical isolates. The discs currently in use and the appropriate organisms for testing are listed in Table 1.

2. Each new batch of Mueller Hinton agar must be tested for unsatisfactory levels of inhibitors. This is done by performing the tests with *E. faecalis* (ATCC 29212) and sulfonamide and trimethoprim/sulfamethoxazole (co-trimoxazole) discs.

C. ZONE SIZE LIMITS

Table 2 (NCCLS Table 3, 3A) lists the maximum and minimum zone diameters (the accuracy) that should be observed with a single control test. Enter zone diameters into the LIS KB-QC charts.

(a) No more than one out-of-control result in 20 consecutive control tests is allowed. Any more than this requires corrective action.

(b) Anytime corrective action is taken the count of 20 begins again.

D. FREQUENCY OF TESTING

1. Each new lot of Mueller Hinton agar must be tested with the control strains when the medium is prepared. In addition media depth, pH and sterility must be tested and documented.

2. Each new lot of antimicrobial discs must be tested with appropriate control strains before being introduced into routine use. Preferably this will be done when the discs arrive in the laboratory.

3. The overall performance of the procedure should be monitored daily. Weekly monitoring will be done in this laboratory provided that the following conditions exist:

(a) documentation that the control strains were tested for 30 consecutive test days

(b) no more than 3 of the 30 zone diameters were outside the accuracy control limits stated in Table 2.

When these requirements are fulfilled, each control strain must be tested:
(i) once a week
(ii) whenever any reagent component is changed.

4. If any zone diameter is outside the control limit when tested weekly, you must return to daily testing until the problem is resolved. If resolution of the problem cannot be documented, you must continue daily control tests. To return to weekly testing, documentation of satisfactory performance for another 30 consecutive days must be done.

E. RESOLUTION OF THE PROBLEM

1. Resolution of any problem must be documented in the LIS as a "Procedure Comment" or "Result Comment".

2. Corrective Action During Daily Testing.

   (a) One out-of-control measurement is not cause for immediate attention.

   (b) Corrective action must be taken if any of the following circumstances arise:

      (i) 2 consecutive measurements of any drug-microorganism combination fall outside the range
      (ii) 3 or more in 20 consecutive test results fall outside the range

3. Corrective Action During Weekly Testing.

   If a zone falls outside the accuracy control/limits, the following are required:

   (a) Appropriate control strain(s) must be tested for 5 consecutive test days.

   (b) For each drug-microorganism combination, all 5 zones must be within the accuracy control limits.

   (c) If any result is outside the accuracy or precision control limits, daily control testing must be resumed for a minimum of 30 consecutive test days.

TABLE 1
ANTIBIOTICS TO BE TESTED FOR KIRBY BAUER QC

	S. aureus ATCC 25923	*E. coli* ATCC 25922	*Ps. aeruginosa* ATCC 27853
Gram Positive			
E	X		
OX	X		
DA	X		
VA	X		
CN	X		
KZ	X		
P	X		
SXT	X		
Gram Negative			
AM		X	
CN		X	X
KZ		X	
CRO/CAX		X	
SXT		X	
TE		X	
F		X	
C		X	
TOB		X	X
CAZ		X	X
CP		X	
PRL			X
AMK			X

Haemophilus (to be tested on Haemophilus Test Medium)

	H. influenzae ATCC 49247
AM	X
CRO/CAX	X
C	X

TABLE 2
ACCEPTABLE ZONE DIAMETERS FOR KIRBY BAUER QC (mm)

	S. aureus ATCC 25923	*E. coli* ATCC 25922	*Ps. aeruginosa* ATCC 27853
E	22 - 30		
OX	18 - 24		
DA	24 - 30		
VA	15 - 19		
CN	19 - 27		
KZ	29 - 35		
P	26 - 37		
SXT	24 - 32		
AM		16 - 22	
CN		19 - 26	16 - 21
KZ		23 - 29	
CRO/CAX		29 - 35	
SXT		24 - 32	
TE		18 - 25	
F		20 - 25	
C		21 - 27	
TOB		18 - 26	19 - 25
CAZ		25 - 32	22 - 29
CP		30 - 40	
PRL			25 - 33
AMK			18 - 26

Haemophilus (to be tested on Haemophilus Test Medium)

	H. influenzae ATCC 49247
AM	13 - 21
CRO/CAX	31 - 39
C	31 - 40

E-TEST QUALITY CONTROL

ANTIMICROBIALS TO BE TESTED:

Penicillin
Ceftriaxone
Vancomycin

ISOLATE FOR TESTING:

Staphylococcus aureus ATCC 29213

FREQUENCY OF TESTING:

Test weekly on the VITEK bench. LIS VITEK QC worklist will generate testing requirement on scheduled day.

PROCEDURE:

The QC organism is subcultured from the TSB slant (in fridge) to BA the day before setting up the QC.

Follow procedure described in the Antibiotic Susceptibility section of the lab manual.

Record results in the LIS E-TEST QC chart.

EXPECTED RESULTS*:

	MIC
Penicillin	0.25-1.0 µg/mL
Cefatazidime	4.0-16.0 µg/mL
Ceftriaxone	1.0-8.0 µg/mL

* As per NCCLS document M7-A3 Table 3.

OUT-OF-RANGE RESULTS:

Enter "Result Comment" in the LIS.
Inform QA or charge technologist of all out-of-range results. Corrective action will be instituted as required.

HIGH LEVEL AMINOGLYCOSIDE RESISTANCE SCREEN PLATE (QUAD) QC

ANTIMICROBIALS TO BE TESTED:

Gentamicin 500 mg/L
Streptomycin 2000 mg/L
Vancomycin

ISOLATES FOR TESTING:

Enterococcus faecalis ATCC 49532
Enterococcus faecalis ATCC 49533
Enterococcus gallinarum ATCC 35038

FREQUENCY OF TESTING:

Test all QC isolates weekly on the VITEK bench with new lot.
Test *Enterococcus faecalis* ATCC 49532 on each plate as they are set up with clinical isolates.
LIS VITEK QC worklist will generate testing requirements as scheduled.

PROCEDURE:

Follow procedure described in the Antibiotic Susceptibility section of the lab manual.

Record results in the LIS QUAD QC chart.

EXPECTED RESULTS:

	Expected results of each quadrant			
	Control	Gent.	Strep.	Vanco.
E. faecalis (ATCC 49532)	+	+	-	-
E. faecalis (ATCC 49533)	+	-	+	-
E. gallinarum (ATCC 35038)	+	-	-	+

OUT-OF-RANGE RESULTS:

Enter "Results Comment" in the LIS.
Inform QA or charge technologist of all out-of-range results. Corrective action will be instituted as required.

REAGENT AND TEST KITS QUALITY CONTROL

REGISTERATION OF REAGENT AND TEST KITS:

Date all reagents and test kits **on receipt**. Register them into LIS and leave the "Active" flag as "N" if the reagent or test kit is not being used immediately.

When reagent or test kit is being placed for use, **date** the **in-use** vial with the date it is opened. If this is a new lot, change the LIS the "Active" flag to "Y" and change the previous lot "Active" flag to "N".

FREQUENCY OF TESTING:

All required QC for reagents and test kits will be alerted to the technologist by the LIS when working up through bench WORKLIST.

Daily QC:

Catalase (all benches)
Oxidase (all benches)
Staph latex (all benches)
Gram stain (Microscopy)

Weekly QC:

Tributyrin (QC bench)
Optochin (QC bench)
MUG (QC bench)
Cephosporin for Campylobacter ID (QC bench)
Nalidixic acid for Campylobacter ID (QC bench)

On Receipt QC:

Bile solubility (QC bench)
ALA (QC bench)
Cefinase (QC bench)
LAP (QC bench)
PYR (QC bench)
Novobiocin (QC bench)
Starch gel sugars (QC bench)
Strep grouping (QC bench)

QC When Test is Performed:

Germ tube
Cetrimide agar
Thermonuclease (Blood Culture bench)

PROCEDURE:

Follow procedure described in the Technical section of the lab manual. Enter the results into the LIS.

OUT-OF-RANGE RESULTS:

Enter "Result Comment" in the LIS.
Inform QA or charge technologist of all out-of-range results. Corrective action will be instituted as required.

EQUIPMENT QC & MAINTENANCE

A. Refrigerators, Freezers, Incubators, Heating Blocks, Centrifuges

1. Temperature and CO_2 levels is checked and recorded daily by the wash-up technician. Report all out-of-range readings to the QA technologist for corrective action.

2. Maintenance such as cleaning and defrosting are done every 3 months or semi-annually. Record all maintenance performed on charts in Equipment Maintenance binder.

B. Instruments (eg. AxSym, BacT/Alert):

See the appropriate sections of the manual for QC items. Record all results into the LIS.

C. Deionized Water:

Resistivity reading is recorded daily by the wash-up technician.
Culture for bacterial count are done weekly.
Report all out-of-range readings to the QA technologist for corrective action.

D. Biosafety Cabinets

Record readings of air flow pressure every time the cabinet is turned on.
Record cleaning and disinfection of cabinet work area on chart as scheduled.

All biosafety cabinets are certified annually by CONTEST. Certificates are filed in the QA section in the store room.

E. Pipette Check

Eppendorff pipettes are checked semiannually by an outside contractor. Records are kept in the Pipette Check folder in the QA section.

F. Isoplater

Weekly
Monthly

Records of all preventive maintenance and repair work performed by maintenance companies are filed in the QA section in the store room.

TML\MSH Microbiology Department Policy & Procedure Manual	**Policy # MI\QC\10\v01**	Page 1 of 1
Section: **Quality Control Manual**	Subject Title: **Serology QC**	
Issued by: **LABORATORY MANAGER**	Original Date: April 11, 2001	
Approved by: Laboratory Director	Revision Date: February 15, 2002	

SEROLOGY QC

All new reagents lots will be tested using samples and/or commercially available reference material (where available) before being placed in service.

All Serology tests require QC run in parallel with each clinical sample test run. Refer to the appropriate tests for procedure and method.

Record all QC results into the LIS.

Inform the charge technologist or senior technologist of all out-of-range results for the appropriate corrective action.

Record all corrective action into the LIS.

QUALITY CONTROL REVIEW

Inform all out-of range results to the Charge Technologist, Senior Technologist or Quality Assurance Technologist.

Charge technologists are responsible for reviewing overdue Quality Control procedures **weekly** with responsible bench technologists.

Obtain lists of overdue QC procedures from the LIS - micqc program:

From micqc main menu

1. go to 1-Tasks
2. select “Results Verification”
3. select from pick list “Bacteriology QC Pending List”, “QC Pending List”, “Virology QC Pending List” or “VITEK Bench QC Pending List”.
4. F12
5. F6 to print list
6. Select printer from printer list

Charge technologist, Senior Technologist or Quality Assurance Technologist will verify all Quality Control results **weekly**. All procedures will be verified on-line.

- Obtain lists for verification from the LIS - micqc program:

  From micqc main menu

  1. go to 1-Tasks
  2. select “Results Verification”
  3. select from pick list “Bacteriology Verification List”, “Heating Block Verification List” or “Virology Verification List”.
  4. Press "enter"
  5. F12
  6. Press F6 on the procedure line
     If there are abnormal results, follow Steps 7 and 8. If there is no abnormal results continue to Step 9
  7. F7 to review action if there are abnormal results
  8. F5 to add new comment/action if needed
  9. F8 to verify all
  10. F12
  11. "y" to confirm editing

12. Repeat steps 6 to 11 for further procedures.
13. F1 to exit when done.

- For Serology tests, QC verifications are done on worksheet for each assay of each run and documented in the LIS (see LIS Manual section for procedure).

The Laboratory Supervisor will perform **Monthly** review of all Quality Control procedures.

- Print the list of abnormal results from LIS-micqc:

  From micqc main menu
  1. go to 1-Tasks
  2. select “Abnormal Res. Rep.”
  3. select from pick list “monthly Abnormal Log”
  4. F12
  5. F7 for report printing
  6. Select printer from printer list
  7. Sign and file this report in the QC Review folder.

- Review on-line all QC procedures from LIS-micqc:

  From micqc main menu
  1. go to 1-Tasks
  2. select “Results Verification”
  3. select from pick list “Supervisor Monthly Verification List”
  4. F12
  5. F7 for report
  6. Select "View" from printer list
  7. Scroll down list to review
  8. "M" then use down arrow to mark a few lines.
  9. "P" to print the marked page
  10. Select printer from printer list
  11. Sign the printed page and file it in the QC Review folder.

- For Serology procedures QC:

1. Log on to **qc**
2. **1.** Result
3. Result **M**aintenance
4. **D**isplay
5. **F2** to list instruments, arrow down to select: AXSYM; INSTB (HTLV); MON; VD or VZ

6. **Enter** to select (asterisk)
7. **F12**
8. **F2** to list tests (8CMS, 8HAB….8VD, 8VZ)
9. **Enter** to select (asterisk)
10. **F12**
11. **F2** to display QC lots (also displays expiratory dates)

    To print or to display more information such as QC verification:
12. **Enter** to select (asterisk)
13. **F12** to pick date range
14. **F12, F7** to print
15. **Sign this report and file it in the QC Review folder.**

	Planting	Blood Cultures	Genitals	C.difficile	Gram Stain	Urine	Vitek	Wounds
Daily	Cabinet pressure Isoplator N2 tank pressure Gram stain slide	Catalase x 2 Oxidase x 2 Staph agglu.x 2 BacT/Alert temp BacT/Alert tape Cabinet pressure Tube coag TDNase Gram stain Heating Blocks	Catalase Oxidase Staph agglu. Heating Block	Kit Control (M-F)	Gram Kohler	Catalase Oxidase Staph agglu. Isoplater Reading Heating Block	Reader temp Change tape QUAD Screen POD Screen Oxacillin Screen	Catalase x 4 Oxidase x 4 Staph agglu.x 4 Tube coagulase Germ tube Heating Block
Weekly	Isoplator	Cefinase					Sensi cards QC KB QC	
When use					Eosinophil stain ZN		Dispenser calibration	
Monthly								
On receipt							ID and sensi cards (on receipt)	
Every 6 months								
Other duties								

	Respiratory	Infection Control	Mycology	QC		Adelino	Serology	Virology
Daily	Catalase x 2 Oxidase x2 Staph agglu. x 2 Bile solubility ALA Heating Block	Catalase x 3 Oxidase Staph agglu. x 3 PYR	Calcofluor (M-F) Cabinet pressure Oxgall Kohler Cornmeal	s/c CO2 Controls (every other day) Heating Blocks		Temp. (M-F)	Cabinet pressure	Cabinet pressure Temp. check
Weekly	Cefinase	Denka		Tibutyrin MUG/Indole Optochin NA CF Bile solubility	Prepared media	CO2 check		Nitrogen tank level CO2 check
When use	ALA	GenProbe Xylose LAP					All test kits	PCP/batch CMV antigenemia/ batch
Monthly				Equipment PM Subculture QC Isolates from freezer Antisera QC		Clean incubator		Clean incubator

	Respiratory	Infection Control	Mycology	QC			Adelino	Serology	Virology
On receipt			Fungal media Rapid Yeast	3% NaCl ALA Antisera QC API BEAA Bile Esculin Bile Solubility Campy Catalase Cefinase CF Choc EBM Eosinophil EV GMSL Gram stain GT HI IMA	Indole (TSB) KV LAP MAC MCPOD MDP Broth ML MSAOX Mueller Hinton MUG/Indole NA NaCl Novobiocin OCBL ONPG Optochin Oxacillin Oxidase PYR QUAD	SMAC Spot Indole Staph agglu. Strep Grouping TCBS Thermometers Todd Hewitt broth Tibutyrin TSI Tube coag Urea ZN		Media
Every 6 months				Pipette check (send-out) Centrifuge check					
Other duties				Trouble shoot QC problems New product evaluation					

										Anaerobic Jars QC																				
										MONTH:					**YEAR:**															
JAR NO.		**1**	**2**	**3**	**4**	**5**	**6**	**7 8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17 18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**
	Indicator																													
	P. aeruginosa																													
	B. fragilis																													
	C. difficile																													
	C. novyli																													
	C. jejuni																													
	Tech																													
	Indictor																													
	P. aeruginosa																													
	B. fragilis																													
	C. difficile																													
	C. novyii																													
	C. jejuni																													
	Tech																													
	Indictor																													
	P. aeruginosa																													
	B. fragilis																													
	C. difficile																													
	C. novyii																													
	C. jejuni																													
	Tech																													
	Indictor																													
	P. aeruginosa																													
	B. fragilis																													
	C. difficile																													
	C. novyii																													
	C. jejuni																													
	Tech																													
	Indictor																													
	P. aeruginosa																													
	B. fragilis																													
	C. difficile																													
	C. novyii *C. jejuni*																													
	Tech																													

APPENDIX IV
BENCH QUALITY CONTROL DOCUMENTATION IN LIS

Bench Daily QC for Softmic

Bench daily QC is to be done on all benches every morning before starting work on specimens. These QCs' include reading temperature(s) of the heating block(s) or instrument associated with the bench, catalase, oxidase, staphylococcus slide agglutination etc.

To document the QC results into the LIS, follow the steps below:

	Keystrokes	**Comment/Result**
Log on to softmic		
1.	2	for "Results"
2.	W	for "Worklist"
3.	pick the specific bench worklist	
4.	F12	for default order range
5.	y	to question: "Would you like to bridge to QC?"
6.	F12	at the QC item list
7.	<enter>	at specific line where QC is done for catalase, oxidase and SS look for the lot number with your bench extension
8.	Enter result for each organism from keypad selection If all results entered are within expected limits, go to Step 15	
9.	If result entered is out of range, a window for result action will show on the screen.	
10.	F2	to look for options for actions to be taken

11. Pick the appropriate action. Enter code "COMM" for comment if none on the list is desired.

12. <enter> <enter> to go to the free text line

13. type in an explanation or corrective action

14. F12 to save result action

15. F12 to save QC results

16. y to answer the question "Confirm editing? "

17. Go to the next QC item(s) and repeat Steps 8 to 16

18. F12, F1 to exit QC list on completing all required QC and return to mic worklist

To enter temperatures for heating block or instrument, go to the line for the equipment

19. <enter> to go into the item

20. type in the temperature recorded e.g. 36

21. F12 to save the temperature entered

22. y to answer the question "Confirm editing? "

To exit QC worklist:

23. F1 you will be back to your bench worklist

If no more new QC is generation the rest of the day, answer the question "do you want to bridge to QC" as "N" the next time you exit and return back to the worklist.

Bench When-done QC for Softmic

For QCs' that are only performed when a test is ordered for a patient.

A. For tests that are associated with the "Media Comment" screen e.g. ALA, Germ tube, Oxgall, Thermonulease

Keystrokes	**Comment/Result**

At the "Media Comment" Screen

1. pick the test required from the keypad e.g. ^ALA

At completing all the result entry for that order:

2.	F12, F12……	to save all the windows
3.	y	to answer the question "Confirm editing? "
4.	y	to the question "Would you like to bridge to QC?" if the test you perform has a result(s) ready.
Or		
	n	If the result(s) of the QC test is not ready.

If answer to this question is "y", enter the QC result, save and proceed with the next specimen.

If answer to the question is "n", go to Step 5.

5.	y	to the question "Would you like to generate QC procedure?"--- there will be a QC item ready for you to enter results the next time you go back to the worklist.
Or		
	n	to the question "Would you like to generate QC procedure?"--- if this is not the first time you order this test and no additional QC is needed.

B. For tests that are usually NOT associated with the "Media Comment" screen e.g. STAT ZN, Eosinophil

	Keystrokes	**Comment/Result**
Log on to softmic		
1.	2	for "Results"
2.	W	for "Worklist"
3.	pick the specific bench worklist	
4.	F12	for default order range
5.	n	to the question: "Would you like to bridge to QC?"
6.	<enter>	to go into the order number for result entry
7.	[or <CTRL n>	to go to the "Media Comment" Screen
8.	pick from the keypad the QC test eg. ^ZNQC	
9.	F12	to save and exit "Media Comment" Screen
10.	F8	to open the window on the "Test Comment" Screen
11.	enter the appropriate result for that test	
12.	F12	to save and close window
13.	<CTRL F>	to status results that do not need verification
	OR	
	<CTRL L>	to status results that need verification
14.	F12, F12……	to save all the windows

15. y to answer the question "Confirm editing? "

16. y to the question "Would you like to bridge to QC?"

17. enter the QC result in the appropriate field(s)

18. F12 to save

19. y to answer the question "Confirm editing? "

You will be back at the worklist for that batch of tests

20. proceed with entering results for the next specimen, do not go to "Media Comment Screen" if no more QCs were done.

Softmicqc for the QC BENCH

Daily Duties

	Keystrokes	**Comment/Result**

Log on to Soft micqc

1. 1 to go to Task

2. e or <enter> at Result entry to go to Result Entry

3. <enter> at the QC worklist

4. F12 to go into QC item list

5. go to each item and enter the appropriate results

If all results entered are within expected limits, go to Step 12

6. If result entered is out of range, a window for result action will show on the screen.

7. F2 to look for options for actions to be taken
8. Pick the appropriate action. Enter code "COMM" for comment if none on the list is desired.
9. <enter> <enter> to go to the free text line
10. type in an explanation or corrective action
11. F12 to save result action
12. F12 to save QC results
13. y to answer the question "Confirm editing? "
14. Go to the next QC item(s) and repeat Steps 5 to13
15. F12, F1 to exit QC list on completing all required QC

Lot Registration

On receipt of any new lot of media, reagent or panel, technologist on the QC bench will enter the new lot numbers into Soft micqc. The results of the QC on the new lots will also be entered into micqc. This is best achieved when the QC work is completed and QC results are ready for entry.

	Keystrokes	**Comment/Result**
Log on to Soft micqc		
1.	2	to go to Registration
2.	type R or M or Panel	for entering either Reagent, Media or Panel
3.	A	to add new lot
4.	F2	at ID: to look up item code

5. <enter> at the item to select

6. F1 at the list to enter a new lot no.

7. Type in date <enter>

8. Type in Expiration date

9. F12 if this is a lot not put in use immediately

   OR

   PageUp <enter> to move the cursor to "Act field

10. Y to change Act field to "active" if this is the lot in use

11. F12 to save

12. Y to question "Confirm editing?"

13. If this media requires QC done on lot receipt, the system will bridge over to enter the results. Enter the results in the appropriate fields.

14. F12, F12…… to save and exit

APPENDIX V
SOFT FOR MICQC

1. Register all items to be QC'd in MICQC (Reagents, media or panels) when received. "On receipt" QC will be generated.

2. Some QC testing is not yet set up in MICQC and is recorded on paper charts. Currently this includes enteric serology testing (monthly), API 20E (on receipt), API 20NE (on receipt), API NH(on receipt)and ETEST(weekly).

3. Reagents, media or panels that have QC done (other than items that are tested "on receipt"only), **must** have an **active** LOT in order for the QC to be generated. Check to see if the **current** lot being used is the same as the **active** lot when performing QC testing. Note also that when an active lot expires, the QC program inactivates it and the QC tests will not generate. When time permits, check that these reagents, media or panels have an active updated lot#. Changing the active lot may result in the generation of duplicate QC procedures (the old lot and the new lot) for a day or two. Cancel the duplicate procedure on the old lot with the comment "Lot not in use".

4. Report all QC exceptions to the QA Technologist (Pauline Lo) or a charge technologist to ensure the appropriate action is taken. Vitek QC exceptions are initialed with a note regarding corrective action taken by the QA Technologist or charge technologist and filed in the Vitek binder.

5. Unusual items for which QC has not been set up can be entered under MEDIA as MISCSOL Miscellaneous Solution. (Enter description and freetext QC results as comment under "F6" results).

6. Separate shipments of the same LOT # are treated as new lots and must be QC'd again. Add –1, -2, etc. to the lot # as necessary to distinguish it from the previous shipment.

7. Vitek panels must be entered in the Vitek QC program when received as well as being registered in MICQC. Vitek sensitivity panels must have a current active lot entered in MICQC in order to generate the weekly VT sensitivity QC. Vitek lots that are no longer in stock should be deleted from the Vitek QC program (under QC lot maintenance).

8. When time permits, check if new lots of reagents, kits, etc. have arrived that have not been brought to the attention of the QC bench. Lists of reagents, media and panels that are to be QC'd are posted by the walk-in frig.

APPENDIX VI
MEDIA FOR QC BENCH ON RECEIPT

Please give the following to the QC bench for registration and QC when received:

1. ALL HOMEMADE MEDIA
2. BILE ESCULIN PLATES AND SLANTS
3. CAMPY AGAR
4. CHOCOLATE AGAR
5. ENTEROCOCCUS AGAR
6. HAEMPHILUS ISOLATION AGAR
7. KANAMYCIN/VANCOMYCIN AGAR
8. MANNITOL SALT AGAR
9. MARTIN LEWIS AGAR
10. MGP BROTH
11. MUELLER HINTON AGAR
12. NACL CONTROL PLATE (ACU)
13. OXACILLIN SCREEN PLATE (ACUO)
14. QUAD (HIGH LEVEL AMINOGLYCOSIDE) PLATES
15. SORBITOL MACCONKEY AGAR

16. TODD HEWITT BROTH

17. TSI

18. UREA

19. VANCOMYCIN SCREEN PLATES

APPENDIX VII
REAGENTS FOR QC BENCH ON RECEIPT

1. ALA discs
2. API 20E strips
3. API 20NE strips
4. API NH strips
5. Arabinose discs
6. Beta glucuronidase (MUG) discs
7. Catalase (hydrogen peroxide)
8. Cefinase discs
9. Cryptococcal Antigen Latex kits
10. DENKA kits
11. Desoxycholate (Bile solubility) droppers
12. E. coli O157 Test kits
13. Eosinophil Stain
14. GonoGen kits
15. Indole spot reagent
16. LAP discs
17. Optochin

18. Oxidase droppers
19. PYR kits
20. Staph-Plus Pastorex kits
21. Strep grouping – A and B reagents
22. Tributyrin discs
23. Tube coagulase
24. VITEK cards (GPI, GNI+,gns-623, gps-105)
25. Xylose discs
26. ZN Stain kits