COUNTY of SONOMA
DEPARTMENT OF HEALTH SERVICES
Mark A. Kostielney - Director

Environmental Health Division
Jonathan J. Krug - Director

February 2, 2004

Peter Kozelka, Ph.D.
USEPA Region 9, WTR-2
75 Hawthorne St.
San Francisco, CA 94105

Dear Dr. Kozelka:

Enclosed is the information you requested about our Department's ocean water monitoring program that includes: latitude and longitude readings for the seven beaches; our Environmental Health Policy and Procedure; and our Public Health Laboratory's Quality Assurance Program.

If there are any questions, please call me at (707) 565-6560.

Sincerely,

Jeff Lewin, R.E.H.S.
Supervising Environmental Health Specialist

JL/

Enclosures

3273 Airway Dr., Ste. D, Santa Rosa, CA 95403-2097 • *phone* (707) 565-6565 • *fax* (707) 565-6525 • www.sonoma-county.org

(52) 1-1

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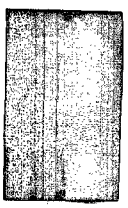

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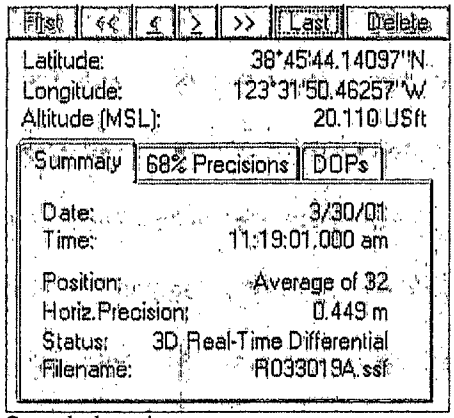
OCEAN BACTERIOLOGICAL MONITORING PROGRAM

1. Gualala



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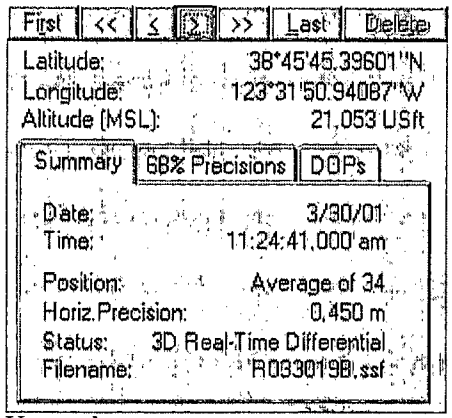

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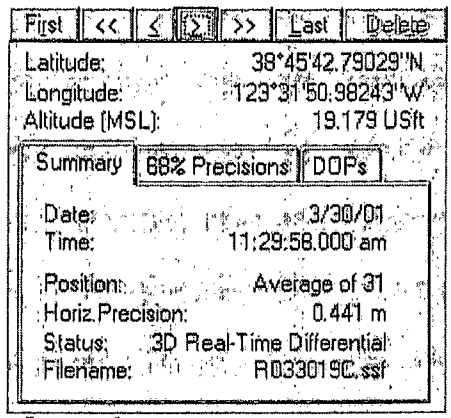
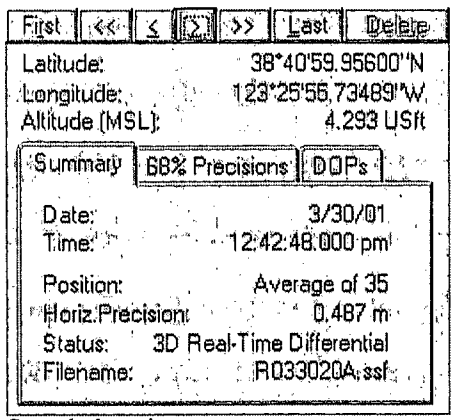


Lower closure

2. Black Point



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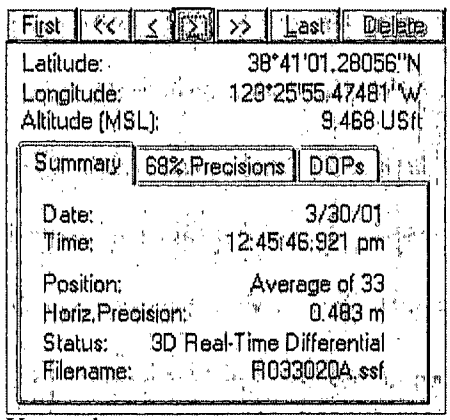

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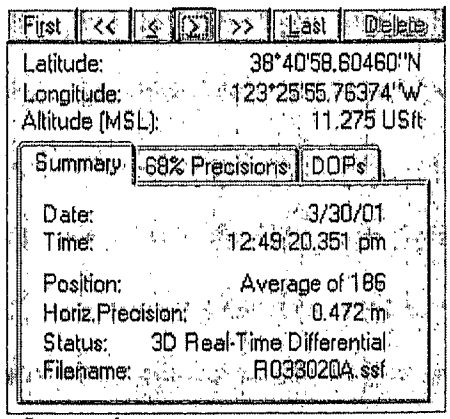
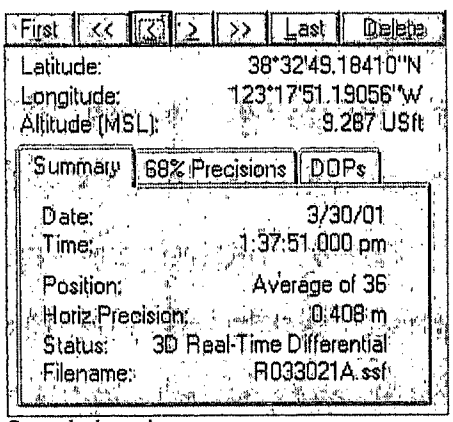


Lower closure

3. Stillwater Cove



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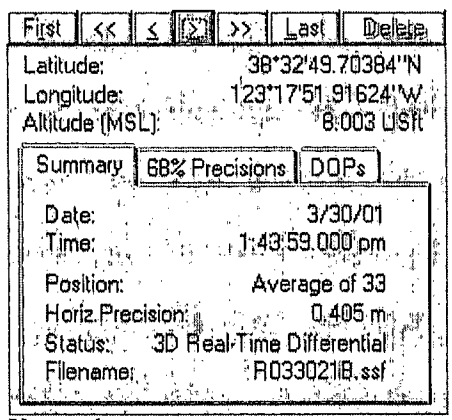

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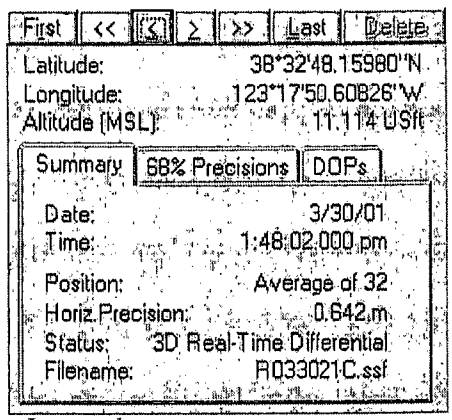
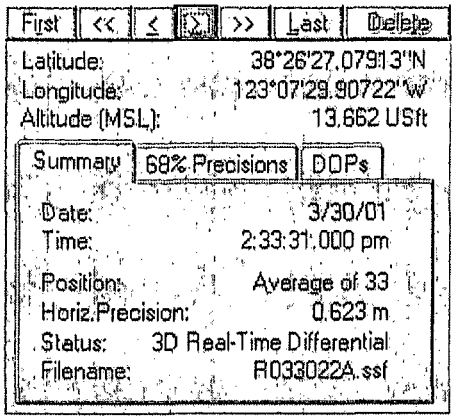


Lower closure

4. Goat Rock



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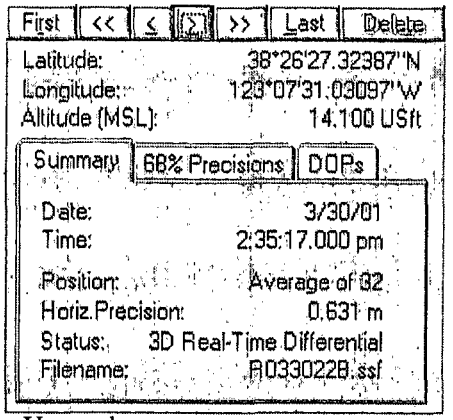

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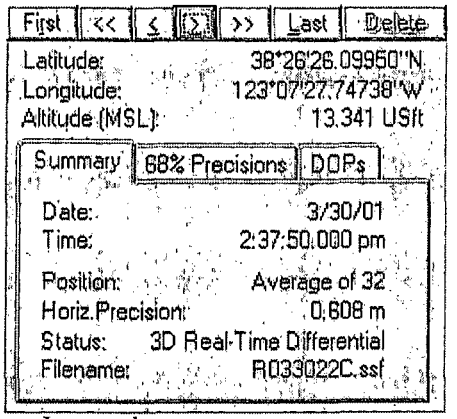
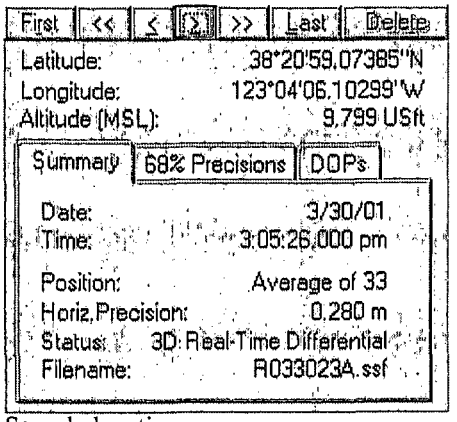


Lower closure

5. Salmon Creek



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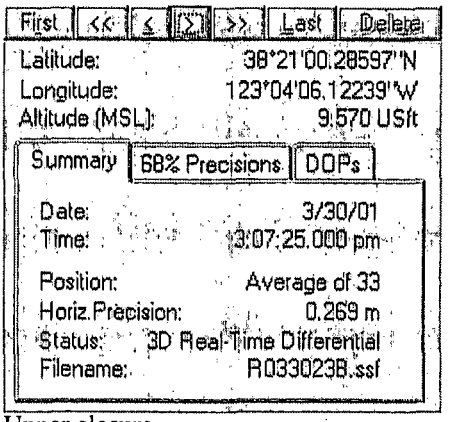

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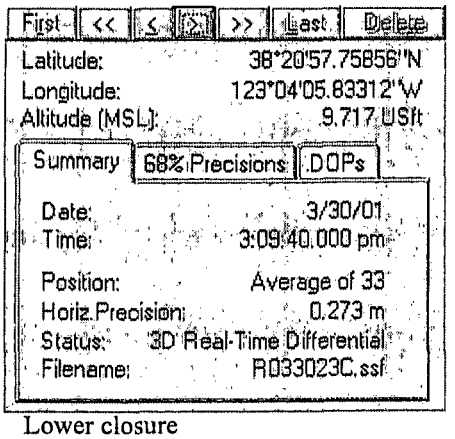
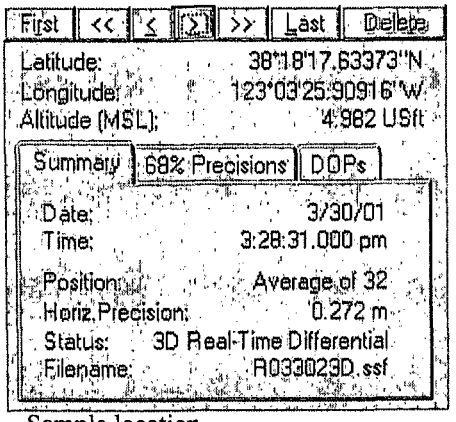


Lower closure

6. Campbell Cove



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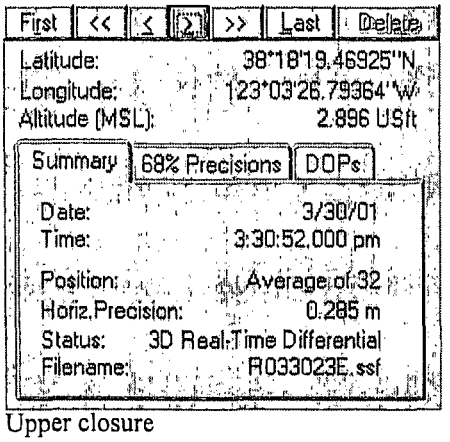

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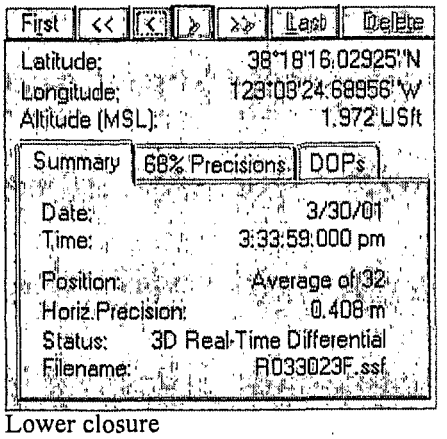
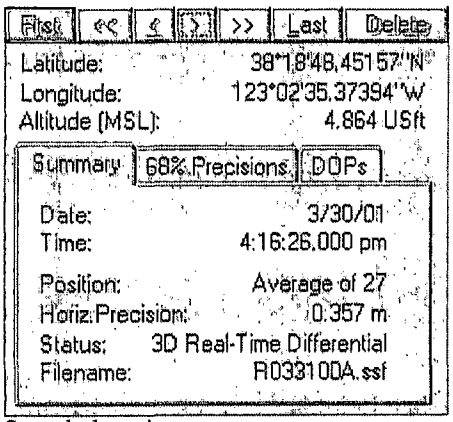


Lower closure

7. Doran Beach



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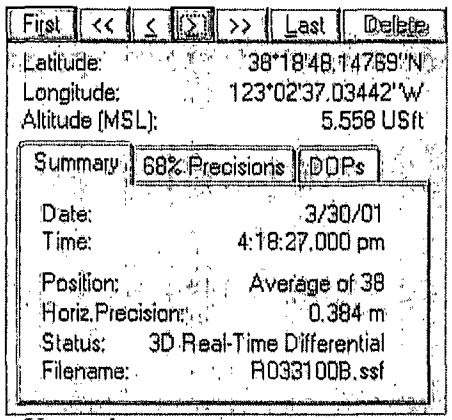

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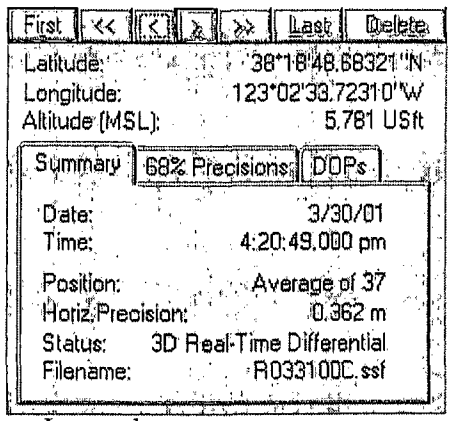

Lower closure

3. Sample approximately 4–24 inches below the water surface.
4. Scoop across incoming wave and replace lid. Make sure as little sand as possible enters the bottle. Leave ample air space in bottle to facilitate mixing by shaking, before examination.
5. Do not contaminate bottle or lid by touching inside of bottle or lid. If bottle or lid is dropped while opened, discard and use a new one.
6. Decant sample to 100-ml mark.
7. Make sure lid is secured to prevent leakage.
8. Information that could be noted by the sampler at the time of collection includes: air temperature, wind direction and intensity, wave size, current direction, water temperature, evidence of sewage, evidence of kelp or algae, number of spectators, birds and other animals in the vicinity. Complete this information on the Ocean Water Lab Slip (Attachment 1).
9. Return to the vehicle immediately and place the bottle in a clean ice chest for transport to the laboratory. An ice chest with sufficient blue ice bags should be used routinely to maintain temperature below 10° C (50° F).
10. Transport to the laboratory. Samples held for longer periods should be kept below 10° C (50° F). Check cooler temperature periodically to be sure samples stay below 10° C (50° F).

B. Safety

1. Although safety may not seem to be a big issue when collecting water samples, anyone who has participated in a sampling program, whether urban or rural, can attest to the risks involved and the importance of exercising caution and awareness when out in the field. In all cases, personal safety comes first and should never be jeopardized for the sake of a sample. If a situation appears too risky, call your supervisor for advice or leave and return when conditions have improved.
2. All individuals collecting samples should be educated about the importance of personal safety issues, which include: appropriate clothing, skin protection, communication and personal protection when in isolated or remote areas, and vehicle safety.
3. It is highly recommended that all samplers be competent swimmers.
4. It is recommended that all samplers have some basic knowledge of first aid.
5. All individuals should receive some instruction about local conditions that could potentially put them at risk:
   a. Identification of poison oak and stinging nettle.
   b. Native wild animals (e.g., ticks, rattlesnakes).

c. Ocean and stream factors (pollution contaminants, including chemical and biological pathogens, underwater obstacles, waves, currents, undertows and tides).

d. Terrain considerations (rocks in and out of the surf zone or along stream beds, slippery banks during wet weather conditions, debris on beaches, potential landslides, etc.).

6. Each sampler should notify the Program supervisor of his or her daily plans for sampling and insure that someone in the office is aware of his or her schedule.

7. Each sampler, when out in the field, should carry some means of two-way communication, preferably a cellular phone or a pager.

C. Lab

Submit samples and Ocean Water Lab Slip to the Public Health Laboratory before 3 p.m.

IV. Results, Notification and Reports

A. Review Data

Check the data to ensure that the numbers shown in the results from the laboratory do not look unusual or contrary to the norm. Resampling may be necessary in these cases.

B. Data Entry

Enter the results in the Environmental Health Beach Testing database (see Attachment 3).

C. Filing

Return ocean water lab slips to the Program Clerk for filing.

D. Notify Government Agencies, Other Interested Parties, and News Media

1. See attached list of government agencies and interested parties to be notified when a beach is to be posted or closed (Attachment 4).

2. See attached sample News Release (Attachment 5) to be used when appropriate to notify the public of postings/closures. The Executive Secretary of the Department's Administrative Section will send out the news release.

3. Ensure that a supervisor or other staff member carefully proofreads the data prior to dissemination.

E. Hotline Recording

Change the hotline recording, if necessary, at phone number 565-6552. See Attachment 6 for examples of information to include in the hotline recording.

V. Posting and Closures

A. Posting

Post a beach with a warning sign when a bacteriological standard is exceeded. Posting with a warning sign alerts the public that there may be an increased risk of illness associated with water contact (see Attachment 7 flow chart for beach posting and closure).

B. Closure

Post a beach with a closure sign where there has been a sewage spill or repeated incidence of exceeding bacteriological standards from an unknown source (see Attachment 8 for examples of warning and closure signs).

VI. Law and Regulations

Attachment 9 is a copy of Assembly Bill 411. Attachment 10 is a copy of the regulations for implementing Assembly Bill 411.

Sonoma City DHS

APPENDIX 4

TABLE OF CONTENTS
QUALITY ASSURANCE PUBLIC HEALTH LAB

QC 1

LAB ORGANIZATION AND PERSONNEL RESPONSIBILITIES

(WATER & SHELLFISH- SECTION)

ORGANIZATION AND RESPONSIBILITY

The staff responsible for-shellfish and water testing is an assigned and trained individual from the laboratory. One analyst at a time will be assigned to the water and shellfish testing. The training shall be approved by the director and dated when training is completed. A form is available for these approval signatures. Periodically there is rotation in the laboratory and a different analyst will rotate with the current water and shellfish analyst. Prior to rotation the existing experienced analyst will train the new analyst according to the written standard operating procedures. The new analyst will perform the following procedures under the supervision and direction of the approved analyst, and when training is completed, the trainer and Lab Director will sign and date the approval from in the procedures manual. The Departmental organizational chart is attached as Exhibit A.

The job descriptions and responsibilities of the Lab. Director and the analysts including the Public Health Microbiologists, Lab. Assistants, Lab. Aide, Clerk Typist III, and Clerk Typist II are filed in the Lab Procedures and QA manual in the laboratory office.

Tests performed in the Shellfish section include the processing of shellfish meats and shellfish waters for presence of coliforms, fecal coliforms and E.coli.

STANDARD OPERATING PROCEDURES :

Standard operating procedures are written in detail and are filed in the Water And Shellfish Procedure Manual. The analyst will perform all testing procedures according to the standard operating procedures.

The microbiologist in the Bacteriology section is designated for back-up duties in the Water and Shellfish section, and he/she shall review all Quality Assurance forms, Quality Control entries and procedures on a monthly basis.

Any deficiencies found shall be brought to the notice of the Lab Director for corrective actions.

QC 2

QUALITY ASSURANCE OBJECTIVES

The objectives are to assure that all the tests and activities we perform in the laboratory are correctly done and there are documented controls to assure that the tests are working as expected.

The analyst checks all lab results going out of the lab and places their initials on the lab slips checked.

The Lab Director or his delegate checks all results sent out of the laboratory daily and initials the worksheets.

The following features are noted:

1) the correctness and clarity of the results
2) the turn-around-times, if they are too excessive for the tests concerned
3) whether the controls were working, where applicable problem lab slips are taken back to the analyst concerned for correction.

All lab staff are evaluated regularly (some are every 6 months, some are once a year, and others are once in two years, depending on the length of service in the county) regarding their performance in the laboratory. This is documented using standardized performance evaluation forms supplied by the county.

Monthly, and at appropriate intervals, the Lab Director checks on the following Quality Assurance documented activities in the laboratory with the analysts concerned:

1) Temperatures of all required incubators, refrigerators, freezers, water baths, air, autoclave, oven, etc. are performed and there are not inconsistencies. All corrective actions are done and documented.

Quality Assurance: Media and Equipment.

A. Media

1) All media will be subject to Quality Control Testing prior to use; See Media Cards (4x6) in Media Lab

2) Procedures for all the Media Quality Controls can be found in the Bact-Chek Procedural Workbook.

C. Distilled Water Quality and Dishwashing: See Suitability

of Deionized Water Log in the Milk Lab

1) SPC, pH and Residual C1, the following tests procedures will be performed:
a) Test for Inhibitory Residues on glassware.
b) pH accuracy is check using commercial pH buffers that are out-dated.
2) Test results will be recorded on the appropriate form and retained in the Laboratory for a minimum of five years.
D. Sample Bottles -Commercially prepared.
1) One sample bottle each month will be tested for sterility.
2) Sterile distilled water will be placed into the bottles, the bottles shaken, and the water checked for sterility by the SPC Method.

Quality Assurance for Colilert Test System: Objectives

1) New Colilert reagent is lot -tested for quality against current lot in use; Colilert performance is QC checked each day of use as follows:
E coli, K. pneumoniae and Ps. aeruginosa are inoculated into sterile water with reagent added.
After 24 hour incubation at 35 C ± 0.5 C the results should show: E. coli: showing yellow color and also fluorescent with UV light.

K. pneumoniae: showing yellow color and no fluorescence under UV light.
Ps. aeruginosa: showing no color change and no fluorescence under UV light.

The above reactions indicate that the new batch of Colilert reagent is acceptable for routine use.
The results are recorded in the water Bacteriology manual under
a) Colilert Reagent lot QC
b) Daily Colilert QC records
2) Daily quality control samples are run concurrently with client specimens. Failure of Reagent Lot or daily QC invalidates the sample test batch.

The following checks are also done for routine QC:
a) incubator temperature and length of incubation of tests.
b) reagent out-dates. Out dated reagents are discarded. New reagents are ordered.
c) the purity of stock cultures used for QCs are checked routinely, at least once every 3 months.

SAMPLING PROCEDURES

Water Sampling procedure: Custody, handling and disposal

Water samples for bacteriological (e.g., coliform) testing are submitted to the laboratory in a 100 ml sterile vial containg a 10 mg. sodium thiosulfate tablet (Capital Vial Inc.) .
The requirements of waters submitted are :

Sampling Procedures:

Recommendations for sampling and preservation of samples can be found in the Standard Methods for the Examination of Water and Waste Water, 19th Edition, 1995.

The oyster meats must arrive at the laboratory within 12 hours after they are harvested, and be stored at 0 to 10 degrees Celsius. They must be set up in broth media within 24 hours of harvest. Telephone contact must be established before oyster meats are submitted to the laboratory.

Sea waters must arrive at the laboratory within 30 hours after they are collected and be stored at refrigeration temperatures of between 0 and 10 degrees Celsius.

Potable waters must arrive at the lab within 24 hours after collection. Rivers and Lake waters must arrive at the lab within 6 hours after collection. Waste waters must arrive at the lab within 6 hours after collection.

If the waters or specimens arrive beyond the time limits specified above, they will be rejected.

Written procedures are available for the following: Methods used for collection of specimens for each test, specimen labeling: specimen preservation; and conditions for specimen transportation.

Procedure for collection of waters:

Sample collection preparation

1. Select a faucet from the cold water supply that will represent a sample of the main water source; i.e., the kitchen tap, etc. DO NOT USE THE HOT WATER SUPPLY.
2. Remove any aerator strainer, or any other device that would restrict the free flow of water from the tap selected.
3. Adjust the water to provide a smooth flow and allow it to run

to waste for 2 or 3 minutes. ,
4. Immediately prior to drawing the water sample, restrict the flow to permit filling of the container without splashing.

Collecting the sample:
5. Unscrew the cap carefully. Do not lay down but hold in one hand while filing container:. Do not touch inside of cap with your hand.
6. Place container under water flow allowing the container to fill to the 100 ml line marked on the container.
7. Replace screw cap tightly. Shake or invert 10 to 15 times. Turn off the tap.
8. Some DON'TS to insure proper collection:
Don't touch the inside of sample container
Don't allow container to touch water tap
Don't rinse out the container
Don't wipe the container
Don't breathe into the container
Don't fill the container to overflowing

SUBMISSION OF SAMPLE TO THE LABORATORY

9. Collect the sample the same day you plan to bring it to the lab. If you are unable to submit the sample within 1 hour of collection, it must be refrigerated. When transporting a sample to the lab, use an ice pack and keep out of direct sunlight. Maximum transit time for samples is 6 hours. {Note: Samples more than 24 hours old are not acceptable for testing)
10. Make certain the lab request form is filled in completely, giving all requested information. Note: Fill in hour of sample collection as well as the day.

QC 4

CUSTODY, HANDLING AND DISPOSAL OF SAMPLES

1. Each sample and the accompanying Water Bact. Laboratory Report Form is given an identifying number:

a. Samples to be tested will be identified with a numbering machine number.
b. Private source samples will be accepted only when accompanied with a copy of the receipt of payment, or a "Pd." mark in the upper left hand corner.

2. Procedures used is described in the 19th edition of "Standard Methods for the Examination of Water and Waste-water" part 9, and/or the latest protocol or manual used or recommended by the California State Department of Health. Written procedures are detailed ahead under blue-divider labeled "2, Procedures"

3. Samples to be tested with the Colilert method: See Water Testing Protocol sheet.

4. Completed water specimens or samples are disposed of by autoclaving in a red plastic biohazard bag and then thrown in the garbage dumpster.

Upon receipt of the specimens, the time and date of specimen arrival are stamped or written on the top right hand corner of the laboratory request slip. The corresponding accession numbers are also recorded onto the specimen. After data entry, worksheets are checked against the "batch verification" list for accuracy. They are then distributed to the appropriate sections of the laboratory. After data entry a red check-mark is placed on the top left hand corner of the lab-slip. Unacceptable specimens are brought to the attention of the analyst in the section and documented onto the lab-slip and work sheet when available, e.g., insufficient specimen, quantity, too long in transit, too hemolyzed, etc. If there are errors in the data entry, corrections are made promptly and after checking against the "batch verification" list. The charge for the specimen must also be credited.
Written instructions are available to clients for the referral or submission of specimens to the laboratory.
When performing tests, the Microbiologists or analysts must make certain that the tests and results are done and recorded onto the correct lab-slip by cross-checking the accession numbers on the specimens and the lab-slips, on each specimen. This will ensure that the results are not erroneously marked onto the incorrect lab-slip.

After marking the results, always check the final copy of the lab. report, and if it is the bottom copy, to make sure that the carbon is in the correct position to transfer the results, or whether the carbon was in place at all. After checking the final copy, the analysts initial their names at the bottom right hand corner of the final lab-slip before placing them into the send-out tray. The Lab Director then checks all the lab-slips against the worksheet prior to giving them to the clerk-typist for sending to the clients. The clerk-typist will also check for lab-slips that have missing carbons when separating the report (e.g., the HIV reports) which still uses carbons for making copies.

Test requisition

The laboratory performs tests only at the written or electronic request of an authorized person. Oral requests for laboratory tests are permitted only if the laboratory subsequently obtains written authorization for testing within 30 days.

Records of test requisitions or test authorizations must be retained for a minimum of two years.
The laboratory must assure that the requisition or test authorization includes:

a) The patient's name or other unique identifier;
b) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for utilizing the test results or the name and address of the laboratory submitting. The specimen, including, as applicable, a contact person to enable the reporting of imminent life threatening laboratory results or panic values;
c) The test(s) to be performed;
d) The date of specimen collection;
e) Any additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results.

The laboratory maintains a record system to ensure reliable identification of patient specimens as they are processed and tested to assure that accurate test results are reported. The specimens all get an accession number each as soon as they arrive in the lab. The same accession number is recorded on the specimen and on the lab slip. The records of all the lab work also identify the personnel performing the testing procedure by initialing their names on every form, paperwork, computer print-out, work-sheet, and work-book. Records of patient testing, including, if applicable, instrument printouts must be retained for a least two years.

The record system provides documentation of information and Includes:

a) The patient identification number, accession number, or other unique identification of the specimen, e.g., HIV codes;
b) The date and time of specimen receipt into the laboratory;
c) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability; and
d) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s) which are necessary to assure proper identification and accurate reporting of patient test results.

The lab director checks results leaving the laboratory to ensure that the turn-around-times are not excessive and there are no errors. All lab tests are performed in the lab on a schedule.

CALIBRATION PROCEDURES AND FREQUENCY
PREVENTATIVE MAINTENANCE

AUTOCLAVE: is checked for mechanical condition quarterly, and is recorded in the autoclave maintenance log found in the autoclave room cupboard beneath the gas burners. Autoclave tape archives are also stored here. Autoclave maximum registering temperature and sterility spore checks are performed weekly and recorded on the autoclave clipboard. Daily run parameters are printed on continuous tap. Problem conditions are corrected by preventive maintenance. All corrective actions are documented in the autoclave maintenance log.

INCUBATOR AND WATER BATH :

Temperatures are checked twice daily and are recorded on temperature log sheets. Monthly archive temperature sheets are stored in the laboratory office. Outlier temperature readings are adjusted immediately by thermostat. This is documented on temperature log sheets. In-use thermometers are calibrated semi-annually against NIST traceable standards thermometer. Thermometer QC records are stored in the milk laboratory. When there are errors that cannot be corrected by adjusting the thermostats, the director will be notified and a service technician will be called in to repair the equipment. The repair will be documented on current month temperature log sheet.

pH METER:

Probe fluid level and KC1 deposits are checked weekly. Fluid is topped up and probe is soaked as necessary. pH meter slope is checked each day prior to use. All pH procedures are found, and records are logged into the pH meter Book found on the pH meter bench. Service is called upon for slope outside of 92-102% range. The standard pH buffers used must be check to ensure that they are not outdated. This is documented in the log book.

WEIGHING BALANCES :

The balances for the weighing of shell fish 'meats and media shall be checked and certified once a year. Certificates are attached to each balance. Balance precision is checked monthly against "S" weights. Results are recorded in Milk Lab QC Book under "BALANCE QC" Any errors found shall be brought to the attention of the Lab Director and corrective actions shall be performed and logged onto BALANCE QC page.

ANALYTICAL & WATER TEST PROCEDURES

1. Colilert tests: the procedure for testing for coliforms and E.coli in potable waters is found in the Waters Procedure Manual.

2. A1 MTF method for the testing of oyster growing waters is found in the Water Procedure Manual.

3. The Quanti-tray procedure for the quantitative testing for coliforms and E.coli is found in the Water Procedure Manual.

4. Samples to be tested by the MTF Method: See Water Testing Protocol sheet. .
a. All samples tested by the MTF Method will be subject to Presumptive Test, and all positive tubes will be confirmed in 2% Brilliant Green Bile Broth (BG) .
1) Samples tested with 5 x 10 ml portions in double strength (2X) Lauryl Tryptose Broth (LTB) .
a) Private water sources
b) Samples that appear to have excessive solids.
c) When specifically requested.
2) Samples tested when an expanded MPN Range is necessary. (15 Tube method, with or without initial dilutionj .5 x 10rnl portions in 2X LTB, 5 x 1 ml port;ions in 1X LTB, and 5 x 0.1 ml portions in 1X LTB.)
a) Sewage suspects.
b) Streams and other surface waters.
c) When specifically requested.
b. Completed Test -See Quality Assurance -Section Bb.

5. Samples to be tested for Fecal Coliform:
a. MTF Method
1) From each Presumptive Positive Tube inoculate a tube of EC Medium coincidentally with a tube of BG Broth.
2) Incubate EC Medium in the Fecal Coliform Water Bath. 24 hrs. ± 2 hrs. at 44.5 C ± 0.2 Degrees.
3) Prepare positive and negative control tubes with each batch.
6. Samples to be tested with a Standard Plate Count:
a. All Swimming pool and hot tubs will be tested with a Standard Plate Count test.
b. Volumes to be plated is 1 ml.

QC 8

VALIDATION AND REPORTING OF DATA

Reporting
a. Final Reports -results will be recorded accurately and completely on report form.
1. Interpretation
a. MPN
*Less Than 1.1 = not Contaminated
*1.1 and Greater = Contaminated
b. After the results have been recorded on the report .form, the distribution of the report is as follows:
1. Environmental Health Samples -Lab keeps green copy; EH gets all other copies
2. Private Samples
a. First carbon copy is mailed to the submitter, the original is filed in the laboratory, and the remainder of the report form is destroyed.

Small Water Systems

Validation and Reporting of Data:

The following procedure is observed when performing water testing for small water systems:

1. If the customer has a small water system they use the gray water lab slip.

2. For a positive water test, e.g., positive coliform, or positive E. coli or fecal coliform we notify the customer by telephone within 24 hours. If a live person is not in, leave a message if they have a telephone answering machine. Fax the results to the State Drinking Water Field Operations Fax phone number is 576.2722.

For smaller water systems, i.e., less than 15 connections and serving less than 25 people, call the County Environmental Health Water Division, phone number (John Anderson, Jeff Lewin 565-6534) .To decide whether to call the State or County depends on many variable factors. If in doubt consult our list posted in the Water Lab wall or in the Water Procedure Book. If the customer is not on that list, phone the customer to find out whom they are responsible to.
Log the phone call, (date and time) on the lab slip and on the log in the water lab. The Analyst who is calling the customer should advise them to call their Drinking Water Field Operations they are responsible to and that they should retest their contaminated waters within 24 hours. They should learn the

details of re-testing from their Drinking Water Field Operations Branch.

3. The Lab Director or designee checks all the water reports after the analysts report the results on the lab slips the clerks then send out the reports to the submitters. The procedure for the send out is in the office procedure manual.

ASSESSMENT OF DATA PRECISION, ACCURACY, VALIDATION AND REPORTING:

Lab director will review water and shellfish worksheets and lab reports for bias, precision and date validation prior to reporting results to submitter. This data assessent will evaluate:

1. Water and shellfish hold time before processing.
2. Incubation time intervals.
3. Transfer time intervals.
4. Proper use of MPN tables.
5. Arithmetic calculationsj correct number of zeros
6. That media quality control is properly applied.

After checking, Lab Director will initial the worksheets prior to send out. Any errors discovered will be brought to the attention of the analyst concerned and corrective actions taken before results are reported.

TEST REPORT:

The laboratory report is sent promptly to the authorized person, the individual responsible for using the test results or laboratory that initially req\lested the test. The exact duplicate of each test report, including final and preliminary reports are retained by the laboratory for two years after the date of reporting. Positive results are phoned or faxed to the clients during office hours between 8 a.m. and 5 p.m. Negative results are mailed or delivered to the clients by courier, depending on the location. The following results are mailed:

a) Blood Bank of the Redwoods
Healdsburg General Hospital
Kaiser Hospitals
Palm Drive Hospital
Petaluma Valley Hospital
Queen of the Valley Hospital
Santa Cruz Medical Clinics
Sonoma County Indian Health
Sonoma County Water Agency
Sonoma Developmental Center

St. Anthony Farms
St. Helena Hospital
SMUDGEO water testing
TPMG Regional
Valley of the Moon Camp
Veteran's Home Clinical
Warrack's Hospital
Windsor Union School District
All water specimen clients

The following results are delivered by courier (negatives and positives) :

Marathon Runner Courier:
b) Common Women's Health Project
Southwest Clinic
Sonoma County courier:
c) Chest Clinic
Community Hospital (Courier envelope/Lab. Assist.)
Sonoma County Jail
Environmental Health
Sonoma County Regional Parks
Sonoma County Permits Resource Mgt.

Pick up at the Lab. by clients:
d) Santa Rosa Memorial Hospital
Unilab
PCL
Public Health Clinical Services
DAAC
Nursing-ATS

Lab. place results into mail slots:
e) Chest Clinic
Early Intervention Center

The laboratory has adequate systems in place to report results in a timely accurate reliable and confidential manner and ensure patient confidentiality throughout those parts of the total testing process that are under the laboratory's control. The test report indicates the name and address of the laboratory location at which the test was performed the test performed the result and if applicable the units of measurement. If the specimens do not meet the laboratory's criteria for acceptability their condition and disposition will be indicated on the test report.

The "normal" ranges is available to the authorized person who ordered the tests or the individual responsible for utilizing the test results. The results or transcripts of laboratory

tests or examinations is released only to authorized persons or the individual responsible for utilizing the test results. The results are phoned or faxed to the clients for imminent life-threatening laboratory results or panic values e.g. , rabies tests on animals that has human contact. The laboratory immediately alerts the individual or entity requesting the test or the individual responsible for utilizing the test results when any test result indicates an imminent life-threatening condition; such persons include the Health Officer the Animal Control Officer the physician of the patient bitten by the rabid animal and the submitter of the specimen if not one of the above.

Upon request by a client, the laboratory will provide information on test methods employed by the laboratory the performance specifications, factors affecting test results and affect the test results or interpretation of test results. This information is available in the procedure manuals, of the respective tests.

The original report or duplicates of test reports is maintained by the laboratory in a manner that permits ready identification and timely accessibility, by filing the duplicate reports chronologically and numerically.

Specimens referred to another laboratory must be sent to a laboratory processing a valid certificate authorizing the performance of testing in the specialty or subspecialty of service for the level of complexity, in which the referred test is categorized.

Our laboratory do not ,revise results or information directly related to the interpretation of results provided by the testing laboratory.

Our laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. We retain or are able to produce an exact duplicate of each testing laboratory's report.

The authorized person who orders a test or procedure must be notified by the referring laboratory of the name and address of each laboratory location at which a test was performed.

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INTERNAL QC CHECKS

QUALITY ASSURANCE FOR COLILERT TEST SYSTEM

1) New Colilert reagent is lot-tested for quality against current lot in use; Colilert performance is QC checked each day of use as follows:
E. coli.,K. pneumoniae and Ps. aeruginosa are inoculated into sterile water with reagent added.
After 24 hour incubation at 35 C ± 0.5 C the results should show :E. coli: yellow color and also fluorescent with UV light.

K ppeumoniae: yellow color and no fluorescence under the UV light.

Ps. aeruginosa: no color change and no fluorescence under UV light.
The above reactions indicate that the new batch of Colilert reagent is acceptable for routine use.
The results are recorded in the water Bacteriology manual under
a) Colilert Reagent lot QC .
b) Daily Colilert QC records

2) Daily quality control samples are run concurrently with client specimens. Failure of Reagent Lot or daily QC invalidates the sample test batch.
The following checks are also done for routine QC:
a) incubator temperature and length of. incubation of tests
b) reagent out-dates. Out dated reagents are discarded. New reagents are ordered.
c) the purity of stock cultures used for QCs are checked routinely, at least once every 3 months.
3) All test problems and failures are documented and reported to the Lab Director. The corrective actions are then taken and documented.

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INTERNAL QUALITY CONTROL:

QC on all equipment instruments reagents, media, glassware, water and accessories is performed at regular intervals according to FDA Quality Assurance publication (5/94)
This chart is found at front of Shellfish Procedures manual.
The laboratory subscribes to annual FDA split sample testing for compliance with federal and state (ELAP) shellfish and water proficiency requirements.

The Quality Control Program consists of:
1. Certification of analyst competence
2. Successful analysis of externally supplied standards, e.g.1 split sample analysis from FDA and ELAP.
3. Proper calibrations of instruments e.g., pH meter, thermometers and water baths as described below.
4. Maintenance of control records and monthly checking of these records by the Laboratory Director.

TEMPERATURE CHECKS

The temperatures of all the refrigerators, room (i.e., air temp) , incubators and water. baths are checked first thing in the morning by the Lab Aide. The CO_2 concentration in all CO_2 incubators are also checked.

The Quality Assurance performed by the Lab Assists, Lab Aide, and PHMs are checked by the Lab-Director once a month, during the first week of the month. The following checks are done:
1) Media quality controls
2) Syphilis serology quality controls
3) Stock culture controls
4) Rabies quality controls
5) Chlamydia quality controls
6) Temperature checks and CO_2 checks
7) TB quality controls: smears, growth of control (Known) cultures, Probes and Bactec controls
8) Hrv quality controls: ErA, Western Blots
9) Milk QC Temp. checked twice a day (am and pm)
10) Water test QC
1,1) T-cell counts: Cytometry QC
12) Autoclave QC
13) Temperature charts recorded in a binder.

Employees found to be deficient in knowledge on skills will be updated by cross-training with a proficient member of the staff, or be sent to the State Laboratory in Berkeley for re-training or up-dating in the areas of deficiency.

Quality Assurance for each section of the laboratory. (What you do routinely to ensure that your tests worked) .
e.g. Serology: check temp. of water bath
check temp of room
check the delivery of the syringes and the
frequency checked.
Use of control sera, strongly positive
weakly positive and
negative
Micropipettes are checked quarterly using the analytical balance. (from the milk, HIV and serology sections)

Use of weakly reactive internal serum and Record all of the above in a book or binder with an index.
The Lab Director checks the quality assurance of each section at least monthly, to assure that all problems are solved satisfactorily and documented.

The test results reported are checked daily by the Lab Director to assure test accuracy, reliability and promptness, and turn-around-times. The laboratory revises as necessary, its policies and procedures based upon the results of those evaluations.

Magnehelic function

The magnehelic readings of the 3 biological safety cabinets are recorded daily. Whenever there is a 0.20 or greater change in the readings, malfunction of the cabinet is suspected. Work stops immediately and the Lab. Director is then notified. Technical Service personnel will be called to check the BSC.

PERFORMANCE AND SYSTEM AUDITS :

Assessment of Precision and Accuracy:

Internal Quality Control and Assurance Checks:

On the first week of the month, the analysts from each section of the lab will discuss QA performance with the Lab Director the Quality Controls and Assurances performed over the past month are audited and checked. The Director checks the data, signs and dates the documents and returns them to the analysts. Any problems discovered in any section will be corrected and discussed with the entire staff.
The performance check is to make certain that all QA activities in the lab are documented and that they are performed at the correct intervals.

PREVENTIVE MAINTENANCE

The lab has a contract with the Sonoma County General Services Department to maintain most of the lab equipment, e.g., incubators, refrigerators, glassware washer, water baths and centrifuges.

The lab has a contract with outside agencies for special equipment e.g., autoclave with Steris Corp biological safety cabinets with Adapt Certification Services Inc.
Services performed by these contractor are documented in the appropriate folders filed in the lab office.

AUTOCLAVE: is checked for mechanical condition quarterly, and is recorded in the autoclave maintenance log found in the autoclave room cupboard beneath the gas burners. Autoclave tape archives are also stored here. Autoclave maximum registering temperature and sterility spore checks are performed weekly and recorded on the autoclave clipboard. Daily run parameters are printed on continuous tape. Problem conditions are corrected by preventive maintenance. All corrective actions are documented in the autoclave maintenance log.

BIOLOGICAL SAFETY CABINETS :
They are inspected and certified once a year.

AUTOCLAVE:
The autoclave and the steam generator are inspected and preventive maintenance performed once every 3 months by the technician from Steris Incorp.

INCUBATOR AND WATER BATH :

Temperatures are checked twice daily and are recorded on temperature log sheets. Monthly archive temperature sheets are stored in the laboratory office. Outlier temperature readings are adjusted immediately by thermostat. This is documented on temperature log sheets. In-use thermometers are calibrated semi-annually against NIST traceable standards thermometer. Thermometer QC records are stored in the milk laboratory. When there are errors that cannot be corrected by adjusting the thermostats, the director will be notified and a service technician will be called in to repair the equipment. The repair will be documented on current month temperature log sheet.

pH METER:

Probe fluid level and KCl deposits are checked weekly. Fluid is topped up and probe is soaked as necessary. pH meter slope is checked each day prior to use. All pH procedures are found and records are logged into the pH meter Book found on the pH , meter bench. Service is called upon for slope outside of 92-102% range. The standard pH buffers used must be check to ensure that they are not outdated. This is documented in the log book.

WEIGHING BALANCES :

The balances for the weighing of shell fish meats and media shall be checked and certified once a year. Certificates are attached to each balance. Balance precision is checked monthly against "S" weights. Results are recorded in Milk Lab QC Book under "BALANCE QC" Any errors found shall be brought to the attention of the Lab Director and corrective actions shall be performed and logged onto BALANCE QC page.

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CORRECTIVE ACTION

All corrective actions are done as soon as possible, and documented.

1) The proficiency test results are discussed with the technical staff. Any corrective actions are performed where needed, and documented.
2) The Lab Director checks that the procedure manuals for every section of the laboratory are updated at least once a year.
3) I.D. of the stock cultures are checked periodically and are viable.

All test problems and failures are documented and reported to the Lab Director. The corrective actions are then taken and documented.

The analysts in every section of the lab (water lab included) meet with the lab director once a month to review and audit all the performance and QA and QC records;
The accuracy and precision of the measured items above are checked and corrective actions taken when needed. All corrective actions are recorded in the manual, located in the lab office.
The QA and QC reports are documented and initialed by the analysts and the lab director. These reports are filed in the lab office.

QUALITY ASSURANCE REPORTS

All Quality Assurance activities are documented and reported to the lab Director.
The reports are then discussed with all the staff that have anything to do with the testing of the specimens.
The reports are then filed in the lab office QA folder.

WATER TESTING QUALITY ASSURANCE

Water Sampling procedure: Custody, handling and disposal

Water samples for bacteriological (e.g. coliform) testing are submitted to the laboratory in a 100 ml sterile vial containing a 10 mg. sodium thiosulfate tablet (Capital Vial Inc.) .

1. Each sample and the accompanying Water Bact. Laboratory Report Form will be given an identifying number:

a. Samples to be tested will be identified with a numbering machine number.
b. Private source samples will be accepted only when accompanied with a copy of the receipt of payment, or a "Pd." mark in the upper left hand corner.

2. Procedures used will be as described in the latest edition of "Standard Methods for the Examination of Water and Wastewater" part 9, and/or the latest protocol or manual used or recommended by the California State Department of Health. Written procedures are detailed ahead under blue-divider labeled "2, Procedures"

3. Samples to be tested with the Colilert method: See Water Testing Protocol sheet.

4. Completed water specimens or samples are disposed of by autoclaving in a red plastic biohazard bag and then thrown in the garbage dumpster.

Analytical Procedures:
3. Samples to be tested with the MF Method: See Water Testing Protocol sheet.

a. 100ml of sample will be filtered and the filter placed on a M-ENDO LES Agar plate.
1) Potable waters submitted by sanitarians.
2) Water sources known not to have a significant background count, i.e., Water Agency, Hospital, etc.

3) Swimming pools hot tubs, (See Section 6) .
4) Ice
5) Samples submitted on an urgent basis.
6) When specifically requested.
b. Verification- See Quality Assurance Section, 8a.

4. Samples to be tested by the MTF Method: See Water Testing Protocol sheet.

a. All samples tested by the MTF Method will be subject to a Presumptive Test, and all positive tubes will be confirmed in 2% Brilliant Green Bile Broth (BG) .
1) Samples tested with 5 x 10 ml portions in double strength (2X) Lauryl Tryptose Broth (LTB) .
a) Private water sources
b) Resample when a prior sample had "No Interpretation" by MF examination.
c) Samples known to be unfilterable or with excessive background counts by MF.
d) Samples that appear to have excessive solids.
e) When specifically requested.

2) Samples tested when an expanded MPN Range (16) is necessary. (9Tube method, with or without initial dilution; 3 x 10ml portions in 2X LTB, 3x1ml portions in 1X LTB, and 3xO.lml portions in 1X LTB.)
a) Sewage suspects.
b) Streams and other surface waters.
c) When specifically requested.

b. Completed Test -See Quality Assurance -Section ab.
5. Samples to be tested for Fecal Coliform:
a. MTF Method
1) From each Presumptive Positive Tube inoculate a tube of EC Medium coincidentally with a tube of BG Broth.
2) Incubate EC Medium in the Fecal Coliform Water Bath. 24 hrs. ± 2 hrs. at 44.5 C ± 0.2 Degree
3) Prepare positive and negative control tubes with each batch.

6. Samples to be tested with a Standard Plate Count:
a. All swimming pool and hot tubs will be tested with a Standard Plate Count along with a Membrane Filter Total Coliform test.
b. Volumes to be plated will be 1ml.

7. Quality Assurance, Media and Eguiprnent.
a. Media
1) All media will be subject to Quality Control Testing prior to use; See Media Cards (4X6) in Media Lab

2) Procedures for Media Quality Control will be found in the Bact-Chek Procedural Workbook.
b. Membranes
1) Only membranes certified by the manufacture as meeting EPA standards will be used (Millipore HA type for Total Coliform)
c. Distilled Water Quality and Dishwashing See Suitability of Deionized Water Log in Milk Lab
1) SPC, pH and Residual Cl, the following tests procedures will be performed:
a) Test for Inhibitory Residues on glassware.
2) Test results will be recorded on the appropriate form and retained in the Laboratory for a minimum of five years.
d. Sample Bottles Commercially prepared.
1) One sample bottle each month will be tested for sterility.
2) Sterile distilled water will be placed into the bottles, the bottles shaken, and the water checked for sterility by the MF Method.

8. Quality Assurance: acquisition and reduction (Not applicable in the Microbiology Lab, for Chemistry Labs only) .

3) Results will be recorded in the Water Analysis Quality Assurance Workbook Sample Bottle Sterility check.
4) Unacceptable Sterility Checks:
a) More bottles will be checked for sterility.
i) If those bottles are not contaminated, bottles may be released.
ii) If any bottle is contaminated, Manufacturer will be notified and requested to replace the shipment of sample bottles.
e. Rinsing/Dilution Buffer
1) Each bottle of rinse buffer and each lot of dilution buffer will be checked for sterility.
a) Immediately prior to use, 100 ml of the rinse buffer will be filtered in a fresh, sterile apparatus and placed on an M-ENDO plate.
b) The last portion of the days rinse buffer will also be filtered in a fresh, sterile apparatus, and placed on an M-ENDO plate.
c) Results will be recorded in the Water Analysis Quality Assurance Workbook Rinse/Distilled Buffer Sterility.
d) UNACCEPTABLE BUFFERS
i) Coliforms present- all reports will be reported as laboratory accident and new sample requested.

ii) Non Coliforms Present -all results that cannot be interpreted will be reported as laboratory accident and a new sample requested.
iii) Contamination lasting two days or more - testing will stop, the microbiologist in charge notified, and the procedure re-evaluated.
8. Procedural Quality Assurance
a. Membrane Filter Verification
1) Every tenth membrane that is positive for coliforms will be subjected to verification.
2) All sheening colonies, up to 20 colonies, will each be picked to a single strength lactose broth tube, and those positive tubes will be confirmed in BG for verification. (We pick 1- 5 colonies)
3) Results will be recorded on the membrane filter verification worksheet (QC-S-16) .Please see Results of QC Tests under "Membrane Filter Confirmation" divider.

4) If any of the following occurs, all sample testing, will stop until the MF Method is re-evaluated and brought within acceptable limits:
a) The number of verified colonies drops below 90% for three (3) consecutive weeks.
b) The number of verified colonies drops below 80% for two (2) consecutive weeks
c) The number of verified colonies drops below 70% for any single week.
b Multiple Tube Method Completed Test
.1) Every tenth sample (potable water source) that is positive after the Confirmatory Test will have all BG positive ~ubes subjected to the completed test.
2) All results will be recorded on the completed test worksheet.
3) If more than 10% of the BG tubes tested with the completed test ori any week are negative, the total "MT" rneth(!)d will be re-evaluated as testing continues.
4) If any of the following occurs, all sample testing will STOP until the MT Method is brought within acceptable (10% NEGATIVE TUBES) 'limits .
a) The number of negative tubes exceeds 10% for three (3) consecutive weeks .
b) The number of negative tubes exceeds 20% for two (2) consecutive weeks.
c) The number of negative tubes exceeds 30% for any one single week.
c. The .microbiologist in the Bacteriology is designated for

back up duties, and he shall review all Quality Assurance forms and procedures on a periodic basis.

9. REPORTING
a. Final Reports -results will be recorded accurately and completely on report form.
1. Interpretation
a. MPN
*Less Than 1.1 = not Contaminated
*1.1 and Greater = Contaminated
b. Membrane Filter -see Attachment 2
b. After the results have been recorded on the report form, the distribution of the report is as follows:
1. Environmental Health Samples -Lab keeps green copy; EH gets all other copies
2. Private Samples
a. First carbon copy is mailed to the submitter, the original is filed in the laboratory, and the remainder of the report form is destroyed.

3. Agencies or systems (i.e., Water Agency, Sonoma State University, etc.)
a. Positive Reports -All positive reports as listed below will be reported immediately (same day) by telephone to:
i. Sonoma County Water Agency -526-5370, ask for Bob Roberson or Neal Parker.
ii. Sonoma State University -664-2317 Plant Operations.
iii.Department of Drinking Water and Environmental Management(DDWEM) Contact Bruce Burton ph: (707) 576-2145 fax.:576-2722
c. All Laboratory copies will be retained either in the laboratory or records storage for a minimum of five years.

QUALITY ASSURANCE FOR COLILERT TEST SYSTEM

1) New Colilert reagent is lot -tested for quality against current lot in use; Colilert performance is QC checked each day of use as follows: .
E. coli, K. pneumoniae and Ps. aeruginosa are inoculated into sterile water with reagent added.
After 24 hour incubation at 35 C ± 0.5 C the results should show: E. coli: showing yellow color and also fluorescent with UV light.
K. pneumoniae: showing yellow color and no fluorescence under UV light .

Ps. aeruginosa: showing no color change and no fluorescence under UV light.
The above reactions indicate that the new batch of Colilert reagent is acceptable for routine use.
The results are recorded in the water Bacteriology manual under
a) ColilertReagent lot QC
b) Daily Colilert QC records

2) Daily quality control samples are run concurrently with client specimens. Failure of Reagent Lot or daily QC invalidates the sample test batch.
The following checks are also done for routine QC:
a) incubator temperature and lenth of incubation of tests
b) reagent out-dates. Out dated reagents are discarded. New reagents are ordered.
c) the purity of stock cultures used for QCs are checked routinely, at least once every 3 months.

3) All test problems and failures are documented and reported to the Lab. Director. The corrective actions are then taken and documented.
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QUALITY ASSURANCE: SPECIMEN LOGGING

Question asks: how are you sure that the specimens are correctly entered, by hand or computer? .
By double-checking the entries by a different person.

Specimen logging in Microbiology, water and milk sections is done by the respective Lab Aide, Lab Assist or Microbiologist. Each specimen is check with the respective lab slip for accuracy in Lab number, patient name or number and testis to be performed on the specimen.

After computer entry, the analysts in the respective sections re-checks the accuracy of the data entry by inspecting the lab numbers and names of the specimens again

In the chlamydia and gonorrhea section, the Lab Aide checks in the specimens, the Lab Assist. or the Microbiologist re-checks the accuracy of the log prior to testing.
The re-checking of all logging of specimens by another person is of utmost importance in the QA of specimen logging. The persons who first log the specimens initial their names in the lower right hand comer of the forms and the persons who re-check the specimens also initial their names at the same location next to the first initials.

On a monthly basis, the Lab Director checks the logs to ensure that these activities are carried out faithfully.