CLINICAL UPDATE

Infection Control in

Endoscopy

MICROBIOLOGICAL TESTING OF GASTROINTESTINAL AND RESPIRATORY ENDOSCOPES AND AUTOMATED FLEXIBLE ENDOSCOPE REPROCESSORS

UPDATED FEBRUARY 2008

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MICROBIOLOGICAL TESTING OF GASTROINTESTINAL AND RESPIRATORY ENDOSCOPES AND AUTOMATED FLEXIBLE ENDOSCOPE REPROCESSORS

In late 2006, it was identified that the section of Infection Control in Endoscopy 2nd edition which provides information on the microbiological surveillance of endoscopes and reprocessing machines needed updating. A multi-disciplinary committee (members listed below) undertook this review in 2007. Broader consultation was also undertaken by various members of that working party and provided valuable input. With changes occurring across the world in endoscope reprocessing technology and standards, it is likely that these recommendations will again require review when the next edition of Infection Control in Endoscopy is prepared. This update has been formatted in the same manner as the section in Infection Control in Endoscopy 2nd edition. A separate listing of references has been provided as some references have been used that are not included in the reference list of that document. We extend thanks to Standards New Zealand for permission to include several flow charts used as a decision guide when positive cultures occur. Please note that the references in those charts refer to sections of the original New Zealand standard and not to this update.

Di Jones. Convenor.
February 2008.

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1 INTRODUCTION

Microbiological surveillance of endoscopes and automated flexible endoscope reprocessors (AFERs) has proven to be one of the most difficult and controversial areas of infection control in endoscopy. Surveillance cultures of endoscopes and AFERs as a quality control measure has been recommended by the Gastroenterological Society of Australia and the Gastroenterological Nurses College of Australia Inc since 19951 and endoscope surveillance cultures were also recommended by the New Zealand Standards Expert Committee in 20022. As a result, the majority of endoscopy units in Australia and New Zealand have routinely been performing these cultures. Endoscope surveillance cultures are also recommended by the French Gastroenterology Society[3], Canadian endoscopy working group[4] , the German Working Group on Hospital Hygeine5, the Robert Koch Institute[6] the Asian Pacific Society of Digestive Endoscopy[7] and the European Society of Gastroenterology and European Society of Gastroenterology and Endoscopy Nurses and Associates have recently published formal guidelines[8] for this practice. In addition, the requirement in European Standard prEN ISO 15883 for the clinical service provider to evaluate outcome quality by technical and microbiological testing of washer disinfectors, endoscopes and water has led to ESGE / ESGENA to also publish guidelines for process validation and routine testing[9]. However, the adoption of microbiological surveillance of endoscopes and AFERs is not universal; the American College of Chest Physicians and American Association for Bronchology[10] and a panel representing a number of United States Gastroenterology and Infection Control groups[11] makes no recommendation for routine surveillance cultures of endoscopes and only 17% of Northeastern USA endoscopy units perform endoscope surveillance cultures[12].

Rationale

Poor compliance with guidelines for endoscope cleaning and reprocessing, occult endoscope damage and faulty or contaminated automated flexible endoscope reprocessors will continue to threaten the safety of patients undergoing endoscopy. Endoscope and AFER cultures have identified breakdowns in infection control before they were otherwise detected or that would not have been detected by other quality control measures[13,14,15,16,17]. Over a three-year period in which more than 7000 endoscope surveillance cultures were performed in 37 New Zealand endoscopy units, one episode of inadequate cleaning and nine episodes of faulty endoscopes (mostly damaged channels) were identified by positive cultures (unpublished data). Some authors reporting recent endoscopy-related outbreaks or pseudo-outbreaks have stated or implied that surveillance cultures could have detected the faults[18,19] and an increasing number of authors are promoting endoscope surveillance cultures[15,16,20,21,22]. Experience in Australia and New Zealand has also shown that the published recommendations for interpretation of positive findings have allowed users to deal appropriately with insignificant contaminants and that negative cultures at a time of minor infection control breakdowns have helped to avoid unnecessary patient recall and testing.

Recommendation

We promote the use of endoscope and AFER surveillance cultures as a quality control marker of the adequacy and completeness of the entire cleaning and disinfection process and the structural integrity of the endoscope. The recommendations for when and how to perform these cultures are based on the international literature and local anecdotal experiences.

2 TESTING WHAT TO LOOK FOR

Bacteria

Bacterial cultures should be directed to the detection of:

In gastrointestinal endoscopes:

- Oral and enteric organisms such as coliforms (including Salmonella), enterococci and viridans streptococci (but not anaerobes) and non-fermentative gram-negative bacilli (including Pseudomonas spp).

In Bronchoscopes:

- As for gastrointestinal endoscopes plus rapid-growing mycobacteria. Culture to identify M. tuberculosis is not included in routine surveillance but should be performed on the next scheduled samples from a bronchoscope that has been used on a patient who has a positive MTB culture.

In Automated Processors:

- Non-fermentative gram-negative bacilli (including Pseudomonas spp.) and rapid-growing mycobacteria.

We do not recommend routine testing for Legionella spp., anaerobes or Helicobacter pylori.

Viruses

Routine microbiological surveillance for viruses is not recommended because:

1. The detection of intact infective viruses is extraordinarily complex, prolonged and expensive, indeed, prohibitively expensive for routine surveillance purposes. Many viruses, e.g. HBV, cannot be cultured in vitro23. The detection of viral nucleic acid by PCR techniques (see Hepatitis C section) certainly does not necessarily reflect the presence of intact infective viral particles.
2. Deva et al[24] have shown that bacterial contamination after reprocessing is an accurate reflection of viral contamination. Where bacteria remained on or in an endoscope after reprocessing there was also frequently remaining viral material. Conversely however, in no case where all bacterial contamination had been removed were remaining intact viruses demonstrated.
3. Viruses can only proliferate within cells. Therefore proliferation in the internal channels of endoscopes or in automated reprocessors does not occur.

3 FREQUENCY OF TESTING

Because of differential risks of infection transmission, recommendations which are themselves empiric, vary with both the proposed use of endoscopes and with the method of disinfection:

1. Automated flexible endoscope reprocessors (AFER's) should be monitored every four (4) weeks.
2. Duodenoscopes should be monitored every 4 weeks.
3. Bronchoscopes should be monitored every 4 weeks.
4. All other gastrointestinal endoscopes should be monitored every three months.
5. Endoscopes which have been processed through a sterilisation cycle and stored in a wrapped state should be monitored every three months.
6. Endoscopes on loan are to be tested within 2 working days of receipt of the instrument. The loan instrument should then be retested according to the schedule for the type of endoscope if it remains on loan for that interval.
7. Further microbiological screening should be undertaken in consultation with a Clinical Microbiologist if:
   - Major changes are made in the Endoscopy Unit personnel responsible for reprocessing;
   - There is a clinical suspicion of cross- infection related to endoscopy;
   - Alterations are made to the plumbing of the endoscopy reprocessing area;
   - New protocols are published;
   - New models of equipment (endoscope or AFER) are used;
   - In response to positive surveillance cultures.

MICROBIOLOGICAL TESTING PROTOCOLS

Instruments should be sampled after usual processing and following storage of at least 12 hours except in the case of endoscopes which have undergone sterilisation and stored in a wrapped state. These should be removed from the packaging and tested at the interval indicated above.

Method of Sampling - Endoscopes

1. 10 mL of sterile water or normal saline is withdrawn from a freshly opened container using a sterile cannula/needle and syringe and put into a sterile specimen container.
2. 10 mL of sterile water is flushed into each of the channels to be brush sampled. Any fluid which emerges from the distal tip is collected into the sterile specimen container.
3. A sterile endoscope brush is passed down the biopsy channel, withdrawn and swirled in the container containing the sterile water. This procedure should also be performed on air and water channels of endoscopes designed with brushable channels. The brush will need to be handled using sterile gloves; sterile gowns are optional. The endoscope brush should be cleaned and sterilised by steam under pressure or low temperature sterilisation prior to sampling.
4. Using a sterile syringe, aliquots of sterile water are flushed through each of the air and water channels, suction channel and the forceps elevator and jet channels where applicable. Flushing should be performed from the

connection points in the light guide plug and flow to the distal tip. The volume of fluid required is different for each endoscope and will vary from 5 to 50 ml. Fluid should be flushed until it emerges from the distal tip. Air is then syringed through to empty the remaining fluid from each of the channels. The total rinse fluid is collected in a sterile specimen container.

5. The samples should be pooled in a single container which is labelled and sent with a request form detailing the following:
   a. Type of scope sampled and serial number.
   b. Name of person to whom report should be sent.
   c. Test requested (see "What to Look For" above).
6. In the event of a positive surveillance culture, the individual channels will need to be sampled and the rinse fluid placed into separate collection containers.

Method of Sampling - AFERs

Early detection of machine contamination is best effected by a concentration process. The method of sample collection for AFER's will vary depending upon the design of the individual machine. Connect a sterile sealed bacteria retentitive 0.2J filter (eg. Millipore) to the outlet of the machine where it normally attaches to the endoscope and cycle at least 200ml of fluid through the filter in the rinse cycle mode. The disc can then be removed and plated directly.

Note: Organisms (especially Pseudomonas spp.) can multiply in fluids. Any delay, such as samples being collected in the late afternoon and not processed until the following day, may lead to erroneous results. Therefore it is essential that the sample is promptly processed after collection. If there is likely to be any delay the sample should be refrigerated.

Laboratory Procedure

1. The collected sample is centrifuged down to 1mL (the entire 1 mL is cultured).
2. The centrifuged sample or microfilter disc is inoculated onto both blood agar and MacConkey agar. The MacConkey agar is incubated aerobically at 35°C for 7 days and the blood agar incubated aerobically at 28°C for 7 days for routine samples. Plates will need to be checked at 48 hours to identify rapidly growing bacteria and attention paid to ensure the plates do not dry out.
3. Semi-quantification of bacterial growth should be performed, e.g. no growth, 1 to 10 colonies, 10 to 100 colonies, 100 to 10,000 colonies, > 104 colonies.
4. Any organisms isolated should be identified to allow interpretation as detailed below; sensitivities are not routinely required.
5. If there is any growth of microorganisms the unit which sent the samples should be notified that working day.

4 INTERPRETATION OF CULTURES

Each endoscopy unit in conjunction with a clinical microbiologist must set its own threshold for the initiation of action if cultures are positive. The flow charts reprinted from the New Zealand Standards[2] in appendix 1 will guide decision making.

In addition, some examples are given below:

1. Low numbers of environmental type organisms, e.g. Staph epidermidis, may be encountered not infrequently. These are most likely to represent collection process contamination rather than a significant problem with the disinfection or cleaning process. The most appropriate initial response is to review the sample processing technique to reduce the chance of contamination.
2. A growth of Pseudomonas spp from a duodenoscope or an AFER that processes duodenoscopes would be cause for serious and immediate concern. This is a high risk clinical situation and the immediate responses would include removing the AFER and duodenoscope from service, careful culturing of the AFER to see if it is the source of contamination, careful inspection of the duodenoscope for defects and repeated cultures after manual reprocessing to see if infection persists and clinical follow up of patients recently undergoing E.R.C.P. and related procedures with that duodenoscope.
3. Significant numbers of enteric organisms, e.g. E coli or Enterococcus faecalis being recovered from one instrument only. This suggests that there is a mechanical defect in the instrument and requires careful inspection with replacement of the channels if no other defect can be identified.
4. Significant or borderline numbers of enteric organisms such as E coli, Enterococcus faecalis being recovered from a variety of instruments within the unit. This is strong evidence of inadequate reprocessing.

It is most likely to be due to defects in the manual cleaning program. Much less likely is a problem in an AFER, (e.g. worn valves, serious biofilm accumulation etc).
The appropriate response here would be a detailed review of all staffs' cleaning and disinfection techniques, if necessary by an independent assessor.

5. Culture of Mycobacterium tuberculosis organisms from a flexible bronchoscope. This is a serious problem. Responses would include removal of the bronchoscope from service, mechanical review of the instrument by the manufacturer, review of any AFER used including detailed cultures and clinical surveillance of patients recently bronchoscoped with that instrument.
6. Growth of Mycobacterium chelonae from a bronchoscope. It is almost certain that this will prove to be due to a contaminated AFER that needs to be taken out of service and decontaminated.
7. ANY isolation of Salmonella or Shigella should cause concern.

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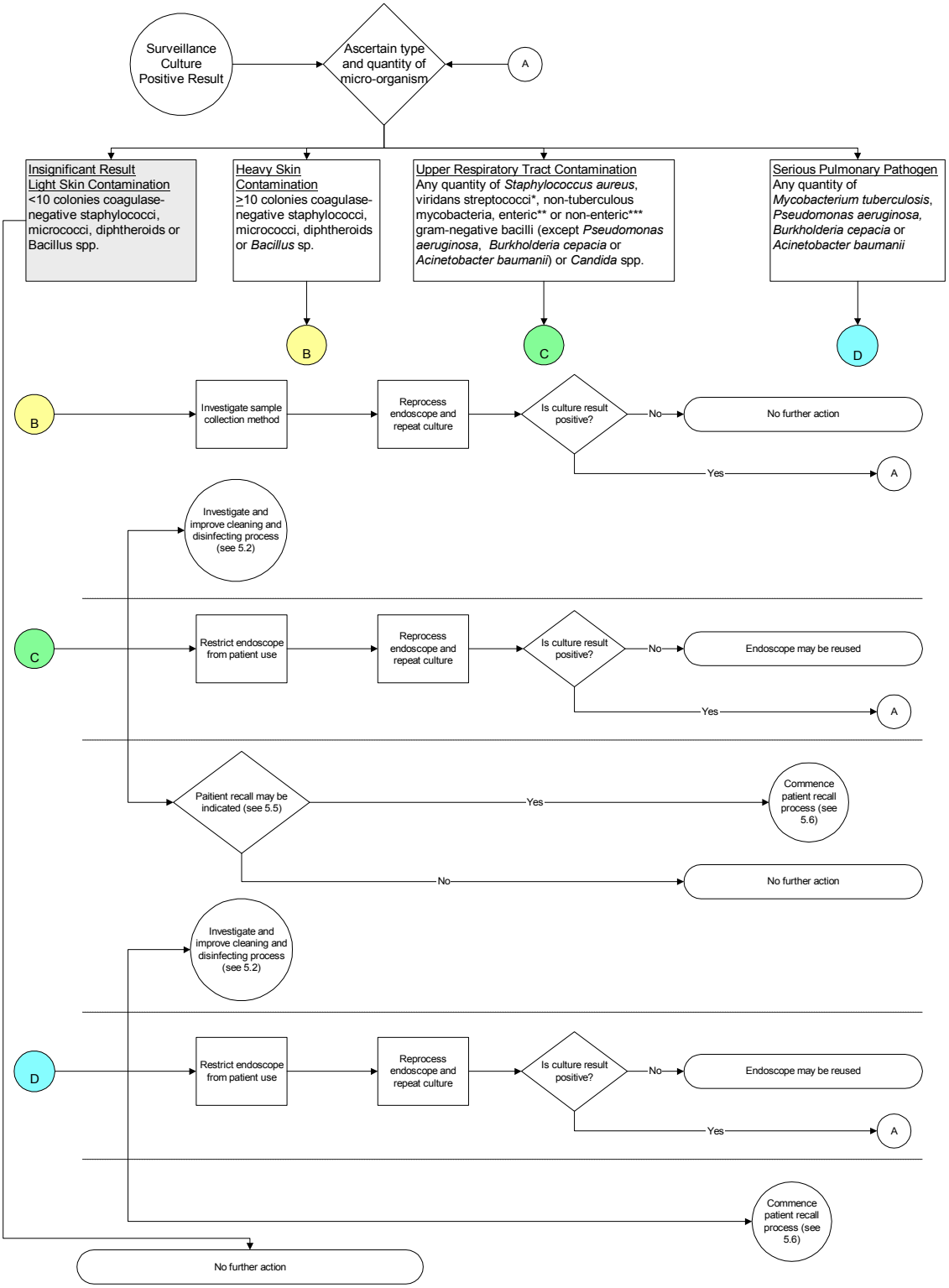
APPENDIX 1
RESPONSE TO POSITIVE BRONCHOSCOPE CULTURES



The horizontal broken lines in each process seperate pathways that must each be followed

* viridans streptococci when found together with coagulase-negative staphylococci, micrococci, diphtheroids or *Bacillus* sp. should be treated as skin contaminants.
**enteric gram-negative bacilli include *Escherichia coli*, *Klebsiella* spp., *Enterobacter* spp., *Serratia* spp., *Morganella* spp., *Citrobacter* spp. and *Proteus* spp.
*** non-enteric gram-negative bacilli include *Pseudomonas* spp. (including *Pseudomnas aeruginosa*), *Alkaligenes* spp., *Flavobacterium* spp., *Stenotrophomonas maltophilia* and *Acinetobacter* spp.

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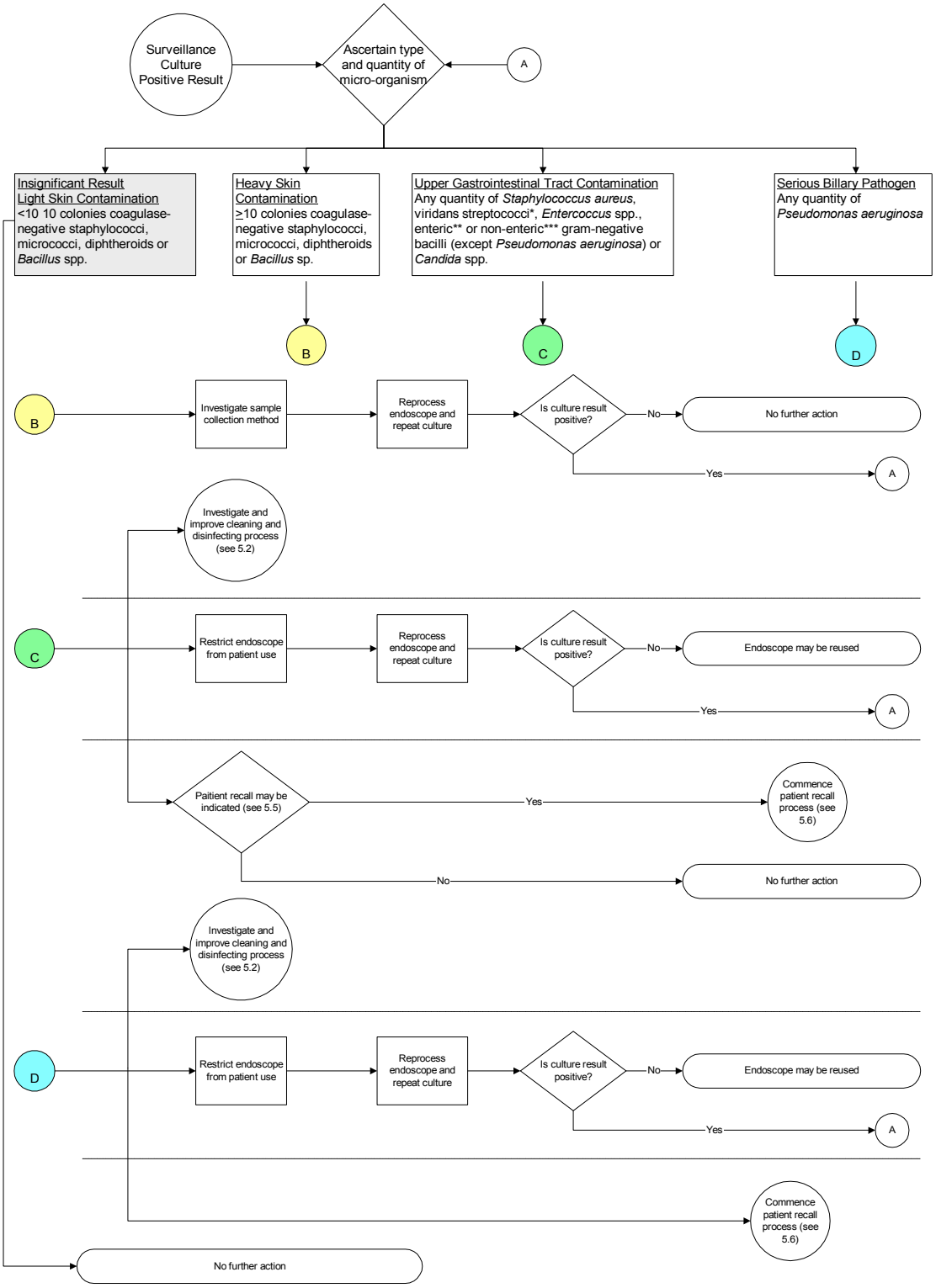
RESPONSE TO POSITIVE DUODENOSCOPE CULTURES



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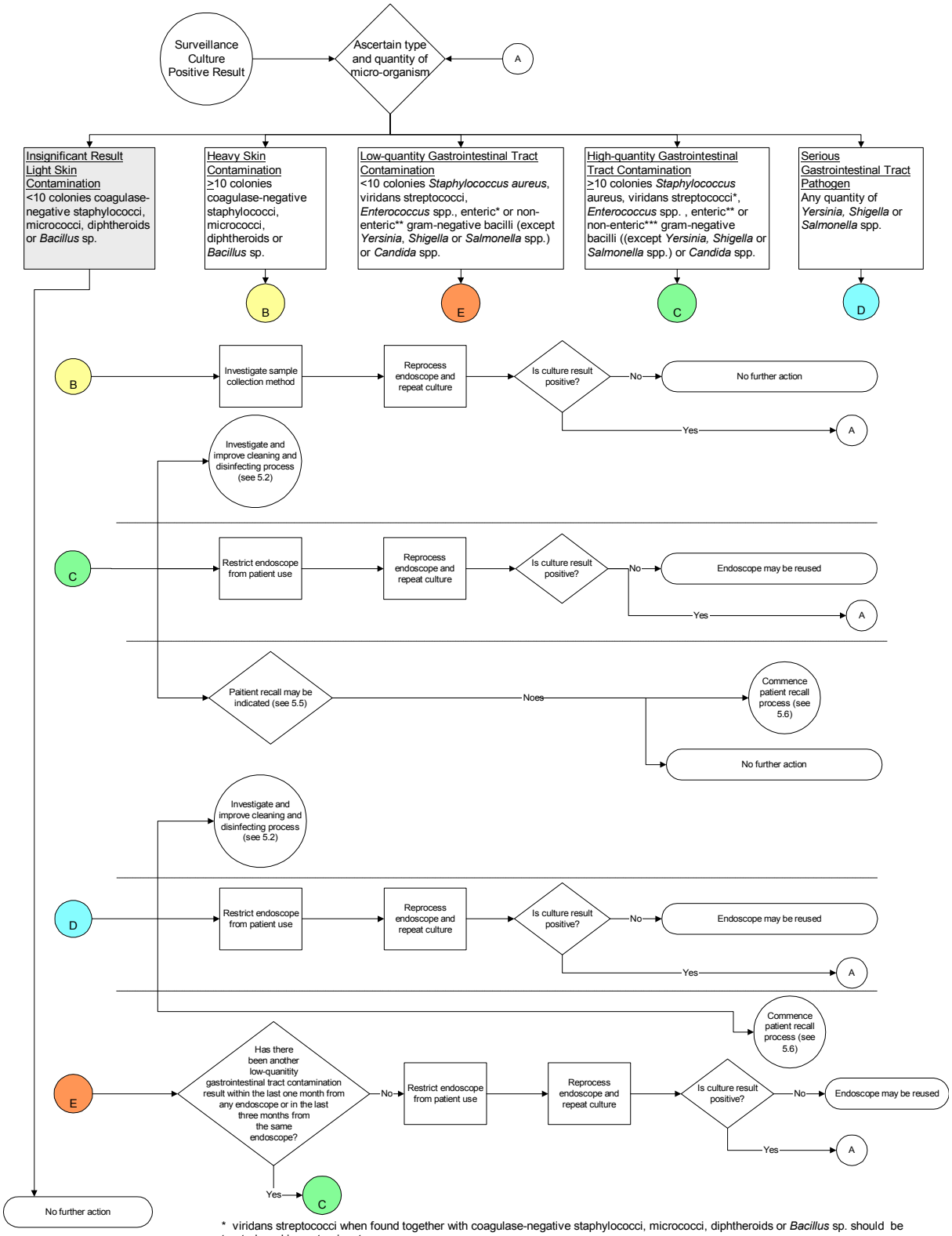
RESPONSE TO POSITIVE GASTROSCOPE OR COLONOSCOPE CULTURES



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