Università degli Studi di Padova
Scuola di Specializzazione in Biochimica Clinica (A.A. 2005-2006)
INDIRIZZI: DIAGNOSTICO E ANALITICO TECNOLOGICO

Biochimica Clinica e Biologia Molecolare Clinica:
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area D SSD BIO/12 ex E05C ore 20 anno IV
-OBIETTIVO FORMATIVO: Acquisire le conoscenze informatiche per la gestione del laboratorio

correzione, verifica e validazione dei risultati

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correzione, verifica e validazione

- ciclo, cicli e deragliamenti
- verifica e validazione nel flusso operativo diagnostico
- verifiche e algoritmi
- autoverifica

CLSI AUTO10-P Vol. 26 No. 4
Autoverification of Clinical Laboratory Test Results; Proposed Guideline

- algoritmi
- correzioni
- verifiche e supervisioni

Collegamento a selAUTO10PE.pdf.lnk

College of American Pathologists (CAP) Checklists

- ***NOTE on CAP PATIENT SAFETY GOALS:***
- *CAP has developed a core set of laboratory patient safety goals for pre- and post-analytic laboratory processes. These goals are:*
- *1. Improve patient and sample identification*
  - a. *At the time of specimen collection*
  - b. *At the time of analysis*
  - c. *At the time of results delivery*
- *2. Improve the verification and communication of life threatening or life altering information regarding*
  - a. *Malignancies*
  - b. *HIV and other infections*
  - c. *Cytogenetic abnormalities*
  - d. *Critical values*
- ***3. Improve the identification, communication and correction of errors***
- *4. Improve coordination of the laboratory patient safety role within healthcare organizations (nursing, administration, POCT personnel, providers)*
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patient safety goals
(CAP) Checklists

- *The inspector should pay particular attention to checklist questions that address the above patient safety goals, and communicate any findings to the inspection team leader, who will address patient safety goal issues with the laboratory director.*

Postanalytic (i.e., post-examination) variables
(CAP) Checklists

- **GEN.20364**
- **Are postanalytic variables monitored?**
- *NOTE: Postanalytic (i.e., post-examination) variables include all steps in the overall laboratory process between completion of the analytic phase of testing and results receipt by the requesting physician. Examples are accuracy of data transmission across electronic interfaces, reflex testing, turnaround time from test completion to chart posting (paper and/or electronic), and interpretability of reports. This list is neither all-inclusive nor exclusive, providing the variables chosen are appropriate to the laboratory's scope of care.*
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revised reports in (CAP) Checklists

- **GEN.41308**
- **Is there a documented system to ensure that all revised reports for previously reported incorrect (erroneous) patient results are identified as revised, corrected, or amended on all forms of patient reports (paper, video displays, *etc.*)?**
  - *NOTE: "Revised reports" means reports that contain any changes to patient results, accompanying reference intervals and interpretations, or patient identifiers, but not minor typographical errors of no clinical consequence. Reports that display revised results must clearly indicate that the new result is a change from a previously reported result.*

revised and original data in (CAP) Checklists

- **GEN.41310**
- **When revised results are reported, are the revised and original data clearly identified as such, and are the original data readily accessible to the user for comparison?**
  - *NOTE: As clinical decisions or actions may have been based on the previous report, it is important to replicate previous information (test results, interpretations, reference intervals) for comparison with the revised information. The previous information and the revised information must be identified as such, and the original data must be present in the revised report (for paper reports), or linked electronically or logically to the revised information (in electronic reports). The precise format of corrected reports is at the discretion of the laboratory. Unless specifically endorsed by the medical staff/clients, it is not acceptable to simply indicate that a result has been revised, with the expectation that the reader will look up the previous result somewhere in the laboratory chart. For extensive interpretive or textual data (e.g., surgical pathology reports), replicating the entire original and corrected pathology reports may be cumbersome and render the revised report format difficult to interpret. In such cases, a comment in the corrected report summarizing the previous information and the reason for the correction may be more appropriate than repeating the entire original report.*

multiple sequential corrections in (CAP) Checklists

- **GEN.41312 Phase I N/A YES NO**
- **When there are multiple sequential corrections of a single test result, are all corrections referenced in sequential order on subsequent reports?**
  - *NOTE: When there are multiple sequential corrections of a previously reported result, it is considered inappropriate to note only the last correction made, as the clinician may have made a clinical decision based upon erroneous data rather than the "true" result. All corrections should be referenced in the patient report.*
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Calculations in (CAP) Checklists

- **GEN.43450**
- **Is there documentation that all calculations performed on patient data by the computer are reviewed annually, or when a system change is made that may affect the calculations?**
  - *NOTE: Errors can be inadvertently introduced into established computer programs. Calculations, algorithms, and/or rules involving reportable patient results must be rechecked and documented to ensure accuracy.*
    - When calculations are performed by an LIS shared by multiple laboratories, this review only needs to be done at one location and each individual laboratory must have a copy of the review documentation.
      However, any calculations specific to an individual laboratory's methodology must be reviewed by that laboratory and the documentation of that review must be available.
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absurd values in (CAP) Checklists

- **GEN.43600**
- **Are system data tables set up to detect absurd values before reporting?**
  - *NOTE: Examples of best practices for this step is to check the result against a defined reportable range and critical values for the test, and ensure that the appropriate number of decimal places are present. An audit trail of this process should exist.*
  -

specimen quality

- **GEN.43750**
- **Does the system provide for comments on specimen quality that might compromise the accuracy of analytic results (*e.g.*, hemolyzed, lipemic)?**

who may use the computer in (CAP) Checklists

- **GEN.43150**
- **Are there explicit documented policies that specify who may use the computer system to enter or access patient data, change results, change billing or alter programs?**
- *NOTE: Policies must define those who may only access patient data and users who are authorized to enter patient results, change results, change billing, or alter computer tables or programs.*
-

identify all individuals in (CAP) Checklists

- **GEN.43800 Phase II N/A YES NO**
- **Is there an adequate system to identify all individuals who have entered and/or modified patient data or control files?**
  - *NOTE: When individual tests from a single test order (e.g., multiple tests with same accession number) are performed by separate individuals and the test result is entered into the LIS, the system must provide an audit trail to document each person involved. For example, a single accession number having orders for electrolytes and a lipid panel may have testing done by two or more individuals. The laboratory should be able to identify the responsible personnel who performed each test and posted the data. This includes sequential corrections made to a single test result. If autoverification is used, then the audit trail should reflect that the result was verified automatically at a given time. With point-of-care testing, if the individual performing the test is different than the individual entering test data into the LIS, both should be uniquely identified by the system and retrievable by audit trail.*
    - REFERENCES: 1) Jones JB. The importance of integrating POCT data into an organized database. *Advance/Laboratory*. 1999;8(9):8-10; 2) Halpern NA, Brentjens T. Point of care testing informatics. The critical care-hospital interface. *Crit Care Med.* 1999;15:577-591.
    -

result entries verified in (CAP) Checklists

- **GEN.43825**
- **Are manual and automated result entries verified before final acceptance and reporting by the computer?**
  - *NOTE: Data entered into the computer system either manually or by automated methods must be reviewed by an authorized individual who verifies the accuracy of the input data before final acceptance and reporting by the computer. An example of best practices for this step is checking the result against the reportable range and critical values for the test. Depending on the local environment, this may or may not require a second person. Verification procedures must generate an audit trail.*
    - *This checklist question does not apply to autoverification procedures (see below).*
    -

Reassay in (CAP) Checklists

- **CHM.15400**
- **Are results falling outside the AMR limits reviewed and reassayed if necessary before reporting?**
  - *NOTE: The AMR is the range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process. Apparent analyte values that are lower or higher than the AMR do not routinely require repeat analysis if the result is reported as less than the lower limit, or greater than the upper limit, respectively, and the laboratory has evidence that the low result is not due to sampling/dilution errors, immunologic "hook effects," etc. In special cases, the procedure should state if an analyte cannot be diluted or concentrated, or if there are limitations to the amount of dilution or concentration that can be successfully used.*
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CLINICALLY REPORTABLE RANGE in (CAP) Checklists

- *The CLINICALLY REPORTABLE RANGE (CRR) is the range of analyte values that a method can report as a quantitative result, allowing for specimen dilution, concentration or other pretreatment used to extend the direct AMR.*
  - *For example, if it is desired to report a result that exceeds the AMR, the specimen is commonly diluted to bring the analyte into that range, the diluted specimen is reassayed, and the final result calculated using the dilution factor.*
- *The establishment of the CRR is a medical judgment made by the laboratory director, and is based in part on the assay technology.*
  - *The CRR is typically established at the time of initial method validation, and it does not need to be re-evaluated unless the methodology changes for the analyte. The method manufacturer frequently will specify the AMR and procedures to use for dilution or concentration of specimens with values outside the AMR. The lower limit of the CRR is typically the lower limit of the AMR of the method, as verified during method validation and stated in the procedure manual. Values lower than this limit will be reported as less than the limit. The upper limit of the CRR is typically not specified unless there is a measurement limitation of a dilution protocol for an analyte. It is acceptable to dilute until a value in the AMR is achieved. The diluent should be specified for each analyte that can be successfully diluted to bring its quantity into the AMR.*

example of a CRRs

An example of a CRR with both low and high limits is given for hCG as follows: Assume that the AMR is 3-1,000 mIU/mL. A laboratory director establishes that, for proper patient/client care, the CRR is 5-1,000,000 mIU/mL. The lower CRR is based on medical judgment that lower values are not diagnostic for pregnancy, while values above the upper CRR are not useful for diagnostic or prognostic purposes. Patient/client specimens with analytical measured results of <3, 3, or 4 mIU/mL are reported as "<5 mIU/mL"; specimens with analytic results >1,000 are diluted and rerun to obtain quantitative values up to 1,000,000 mIU/mL; specimens with analytic results >1,000,000 mIU/mL are reported as ">1,000,000 mIU/mL".

An example of a CRR with only a low limit is given for aspartate aminotransferase (AST) as follows: assume the AMR is 4-900 IU/L. A laboratory director establishes that numeric values <4 are not clinically useful, while values >900 are clinically useful. Patient/client specimens with measured results of <4 are reported as "<4 IU/L"; specimens with analytic results >900 are diluted and reassayed until a quantitative result is obtained. In this case, the upper CRR is not specified because specimens are diluted until a quantitative value is obtained.

COMMENTARY: Upper and lower limits of the analytical measurement range (AMR) for all analytes must be defined. Results that fall outside these limits must be appropriately reviewed and reassayed if necessary before reporting.

REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7164 [42CFR493.1253(a)].

dilution protocols in (CAP) Checklists

- **CHM.15500 Are dilution protocols and diluents (or concentration protocols) specified for all methods for which the CRR exceeds the AMR?**
  - *NOTE: When a test result exceeds the AMR, the laboratory may dilute or concentrate the specimen to adjust the analyte content to be within the AMR, then repeat the assay to obtain a quantitative result. The procedure manual must include the protocol for dilution or concentration, any diluents or other components used in the process, and the calculation of the final reportable result. If there is a limit to the amount of dilution or concentration that is appropriate for an analyte, the procedure must state the limit, and specify how to report results that exceed the CRR.*

technical supervisors in (CAP) Checklists

- **GEN.53500 Phase II N/A YES NO**
- **Do the technical supervisors fulfill the responsibilities defined by CLIA-88?**
  - *NOTE: The technical supervisors of high complexity testing, as designated by the laboratory director, are responsible for the technical and scientific oversight of the laboratory. Specific details are found in Fed Register. 1992(Feb 28):7180-7181 [42CFR493.1451].*
    - REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 1992(Feb 28):7180 [42CFR493.1451].

general supervisor in (CAP) Checklists

- **GEN.53700**
- **Does the general supervisor fulfill the responsibilities defined by CLIA-88?**
  - *NOTE: The general supervisor of high complexity testing, as designated by the laboratory director, is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. Specific details are found in Fed Register. 1992(Feb 28):7182 [42CFR493.1463]*
    - REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 1992(Feb 28):7182 [42CFR493.1463].

Owner, director, supervisor(s), clinical consultant(s), and general supervisor(s) in (CAP) Checklists

- **GEN.54000**
- **Is there an organizational chart for the laboratory, or a narrative description that describes the reporting relationships among the laboratory's owner or management, the laboratory director, technical supervisor(s), clinical consultant(s), and general supervisor(s), as appropriate?**

Competency in (CAP) Checklists

- **GEN.55500**
- **Has the competency of each person to perform his/her assigned duties been assessed?**
- *NOTE: The manual that describes training activities and evaluations must be specific for each job description. Those activities requiring judgment or interpretive skills must be included. The records must make it possible for the inspector to determine what skills were assessed and how those skills were measured. The competency of each person to perform the duties assigned must be assessed following training, and at least annually thereafter. During the first year that an individual tests patient specimens, competency must be assessed at least every six months. Retraining and reassessment of employee competency must occur when problems are identified with employee performance. Competency assessment for each individual must include all of the following elements that are applicable to the individual's duties:*
  - *1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing*
  - *2. Monitoring the recording and reporting of test results*
  - *3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records*
  - *4. Direct observation of performance of instrument maintenance and function checks*
  - *5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and*
  - *6. Evaluation of problem-solving skills*

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Competency in (CAP) Checklists

- **GEN.55500**
- **Has the competency of each person to perform his/her assigned duties been assessed?**
  - REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Oct 1):1065-66 [42CFR493.1451(b)], 1053-54 [42CFR493.1413], 1992 (Feb 28) 7184 [42CFR493.1713] ; 2) Tiehen A. Competency assessment in the transfusion service. *Med Lab Observ.* 1993;25(10):35-42; 3) Harmening DM, *et al.* Defining the roles of medical technologists and medical laboratory technicians. *Lab Med.* 1995;26:175-178; 4) NCCLS. Training verification for laboratory personnel; approved guideline GP21-A. Wayne, PA: NCCLS, 1996; 5) Blacklidge L. Professional perspectives. Why I hire certified technologists. *Lab Med.* 1999;30:503-504; 6) Boone DJ. Assessing laboratory employee competence. *Arch Pathol Lab Med.* 2000;124:190-191; 7) Howanitz PJ, *et al.* Employee competence and performance-based assessment. A College of American Pathologists Q-Probes study of laboratory personnel in 522 institutions. *Arch Pathol Lab Med.* 2000;124:195-202; 8) Church DL, *et al*. Effects of restructuring on the performance of microbiology laboratories in Alberta. *Arch Pathol Lab Med.* 2000;124:357-361; 9) Ward-Cook K, *et al*. Medical technologist core job tasks still reign. *Lab Med.* 2000;31:375-379; 10) Haun DE, *et al.* Assessing the competence of specimen-processing personnel. *Lab Med.* 2000;31:633-637; 11) Schiffgens J, Bush VA. Four-part approach to competency assessment. *Lab Med.* 2001;32:431-435.

analyst performing or completing (CAP) Checklists

- **GEN.41306**
- **Is there a system whereby the identity of the analyst performing or completing the test and the date of the test can always be established?**
  - *NOTE: The system should also be capable of identifying those test results that have been autoverified.*
    - REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7162 [42CFR493.1283(a)(4)].
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24 hours review in (CAP) Checklists

- **CHM.10900**
- **Are the results of tests performed in the absence of on-site supervisors reviewed by the laboratory director or general supervisor within 24 hours?**
  - *NOTE: The CAP does NOT require supervisory review of all test results. This question addresses only that situation defined under CLIA-88 for "high complexity testing" performed by trained high school graduates qualified under 42CFR493.1489(b)(5) when a qualified general supervisor is not present.*
    - REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7182 [42CFR493.1463(a)(3) and 42CFR493.1463(c)]: 7183 [42CFR493.1489(b)(1) and 42CFR493.1489(b)(5)].
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- AAMI TIR No.18—1997, Guidance on Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical Engineers—Part 1: Radiated Radio-Frequency Electromagnetic Energy

- ISO/TR 21730:2005(E), Health informatics – Mobile wireless communication and computing technology in healthcare facilities – Recommendations for the management of unintentional electromagnetic interference with medical devices.

The following flow diagram is an example of a simple algorithm for evaluating the BUN/creatinine ratio in human serum. The diagram is based on the use of an enzymatic BUN method, as well as an enzymatic method for creatinine. The algorithm complexity could be increased depending on the information available.

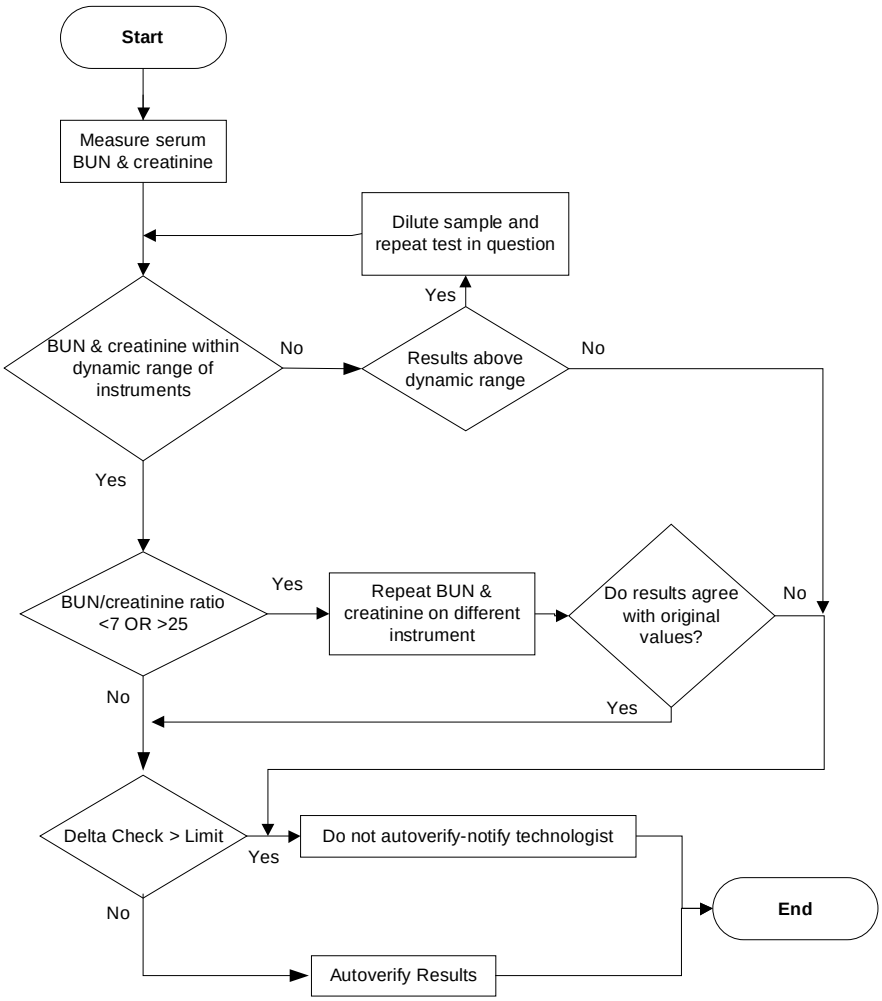

Figure 1. Example of a Simple Algorithm

The following flow diagram is provided as an example of a complex algorithm that deals with artifactual hyponatremia. If a sodium measurement is done on a patient's serum or plasma containing either very high levels of lipidemia and/or paraproteinemia, there can be an artifactual lowering of sodium levels if the chemistry analyzer does the assay on a diluted sample.

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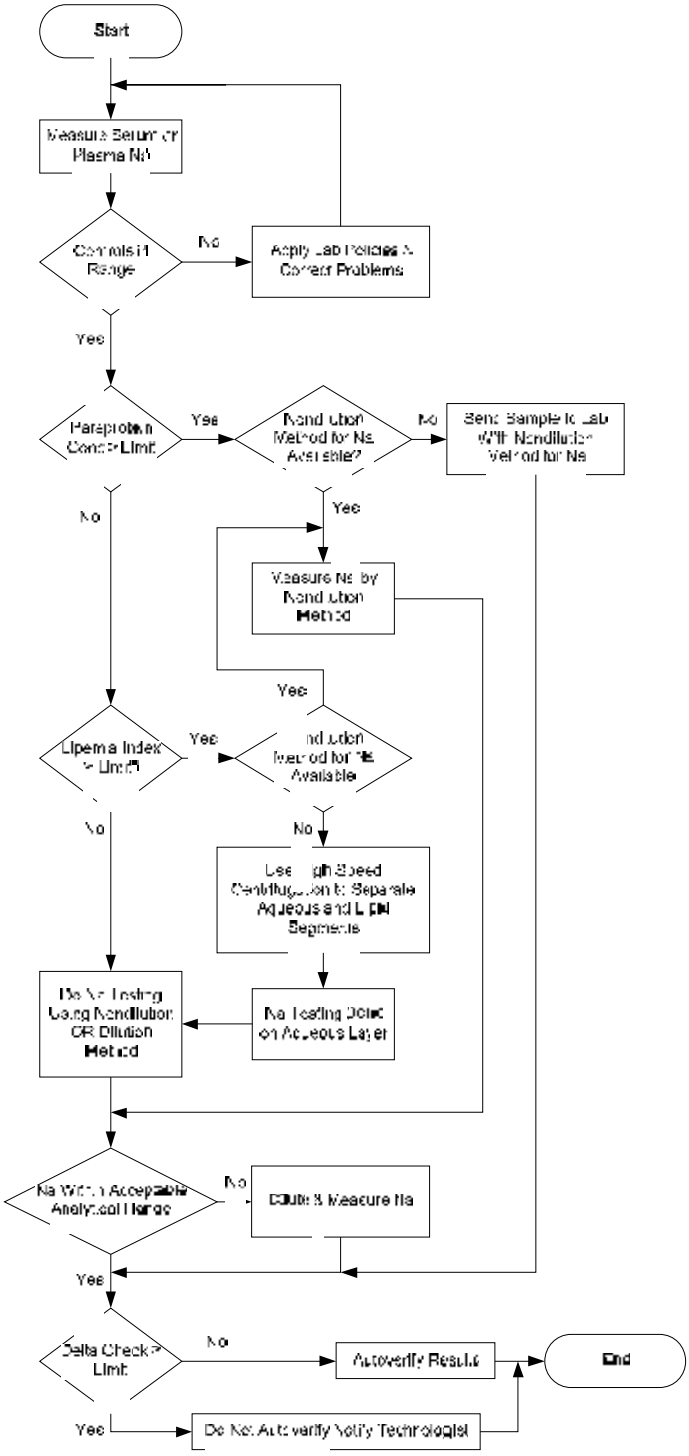

Figure 2. Example of a Complex Algorithm

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