

**UNDER THE HEALTH AND  
DISABILITY SERVICES ACT 1993**

**IN THE MATTER OF THE  
MINISTERIAL INQUIRY INTO THE  
UNDER-REPORTING OF CERVICAL  
SMEAR ABNORMALITIES**

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**STATEMENT OF EVIDENCE OF  
GRAHAM DOUGLAS WALKER**

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**TELARC/IANZ**

**I, GRAHAM DOUGLAS WALKER**, Programme Manager, state:

1. Until March 2000 I was the Programme Manager, Medical Testing and Radiology, of International Accreditation New Zealand (“IANZ”). I joined IANZ in early 1992 in the Mechanical and Applied Physics programme, but took up my present position in early 1993.
2. Prior to 1997, IANZ was known as Telarc New Zealand. For convenience, I will refer to it in this statement as Telarc.
3. When I became Programme Manager, Medical Testing and Radiology in 1993, approximately 40 percent of medical laboratories in NZ were accredited with Telarc. Part of my role was to promote the accreditation services offered by Telarc.
4. Annexed as **Exhibit GDW/IANZ/0001** is a summary of the Medical Laboratories that shows the date each Laboratory was accredited, the date the Cytology Department was accredited, and the date of any suspensions of accreditation. Of the laboratories or units listed in the table as being suspended or inoperative or withdrawn, only three have been reinstated, being NZ Blood Service, Gisborne Hospital Biochemistry and Marlborough Medical Laboratory. Healthcare Hawkes Bay has 3 units withdrawn and 7 are operative. One of the main reasons for suspension or withdrawal is because the laboratory has discontinued performing those particular medical tests, either permanently or because of staff or other internal changes.
5. This summary shows that Gisborne Laboratories Limited, now called Medlab Gisborne, obtained accreditation on 2 December 1997.
6. To the best of my knowledge, at present there are only 4 or 5 medical laboratories that are not accredited and none of those are involved in performing anatomical tests such as cytology or histology.

### **Cost of Accreditation**

7. I refer to the exhibit produced by Sylvia Sax as **SS/HFA/0034**. I confirm this as being a letter I wrote to her in response to a request for information about the cost of accreditation.
8. To clarify, where it indicates that the cost of accrediting a small laboratory, with 3 to 4 units, would be \$6,000 to \$8,000, a “unit” refers to an Accreditation Unit, which in turn represents a single medical testing discipline, such as Cytology.
9. The cost of accreditation for a Cytology Unit would therefore be approximately \$2,000.

### **Gisborne Laboratories Limited**

10. In June 1993, Telarc received a letter dated 14 June 1993 from Mr Reeve, Manager of Gisborne Laboratories Limited, requesting information on registration with Telarc, which I produce as **Exhibit GDW/IANZ/0002**.
11. Telarc’s records do not show any prior correspondence or meetings with Gisborne Laboratories Limited (“Gisborne Laboratories”) concerning accreditation.
12. As a result of the inquiry in June 1993, I went to Gisborne Laboratories on 26 October 1993 to discuss the accreditation process with Mr Reeve. Discussions were primarily with Mr Reeve but I was also introduced to Dr Bottrill and had brief discussions with him.
13. On or about 27 June 1994 Telarc received an Application for Registration from Gisborne Laboratories dated 17 June 1994. A copy of this Application is annexed as **Exhibit GDW/IANZ/0003**.
14. The Application shows that the initial registration was sought for the Cytology/Histology Department, which comprised one pathologist and one assistant.

It also states that Gisborne Laboratories had no other accreditations at that date. The Application further indicates that the laboratory would be ready for assessment for accreditation on 25 July 1994, just over one month following its application. This time-scale, I believe, indicates a lack of understanding of the requirements of accreditation, despite my previous visit in October 1993. Preparation to meet the accreditation requirements more usually takes between 12 months to 2 years.

15. By letter dated 27 June 1994, Telarc acknowledged receipt of Gisborne Laboratories' Application and advised that I would now handle their application, and that I would contact them to make arrangements for the initial assessment of the Laboratory.
16. Arrangements were then made for me to visit Gisborne Laboratories for a pre-audit consultation in respect of the Cytology/Histology Department, which I did on 25 October 1994. The purpose of this visit was to assess where the Laboratory was currently positioned regarding accreditation, and to identify any areas where it fell short of the accreditation requirements.
17. While the invoice sent prior to my visit indicated that I would spend three hours, my recollection is that I spent up to five hours at Gisborne Laboratories during that visit on 25 October 1994. This was not unusual as, at that time, Telarc routinely absorbed the cost of additional time as part of its efforts to encourage accreditation of laboratories. Further, the approximately five hours spent at the Laboratory would not have included time reviewing the Quality Manual prepared by Gisborne Laboratories for accreditation purposes. I would have reviewed the manual before the visit on 25 October 1994.
18. During my visit to Gisborne Laboratories on 25 October, I met with Mr Reeve and had brief discussions with Dr Bottrill and other laboratory staff.
19. Having carried out a large number of pre-accreditation consultation visits prior to the one with Gisborne Laboratories, I was usually able to determine fairly early on in a visit whether there was a genuine interest and commitment to obtaining accreditation.



21. It was my clear impression from my visit to Gisborne Laboratories that accreditation was not being actively pursued by the Laboratory, and that the process was being pursued begrudgingly for other reasons. Although I cannot now recall the exact words, Mr Reeve and Dr Bottrill as much as told me that the laboratory needed to demonstrate for contractual purposes that it was working towards accreditation.
22. Following my pre-audit consultation visit with Gisborne Laboratories, I sent a written report outlining the areas that I had identified as not being in compliance with accreditation requirements (“the report”). The report is dated 3 November 1994, and is annexed as **Exhibit GDW/IANZ/0004**.
23. The report sets out non-compliance in two separate areas: quality systems, which relate to the quality manual and systems, and technical, which covers the requirements of good laboratory practice, competence of staff, equipment, environment, etc. The technical and competency requirements are, in my view, the most important and the most vital to running a competent laboratory, and not too much should be read into the deficiencies with the quality manual outlined in the report.
24. In the technical category, however, I had not either then or since visited another medical laboratory that has been as deficient in the major areas as Gisborne Laboratories. I can say this with a high degree of assurance because in my role I have personally visited all of the medical laboratories at least once, and many several times.
25. Telarc staff are, however, not in a position to notify anyone of concerns resulting from assessment of laboratories, and are contractually bound not to disclose findings that result from access to a laboratories documents through the assessment procedure. Accreditation with Telarc has always been voluntary, and it would be a disincentive for laboratories to seek accreditation if Telarc was seen to be acting on behalf of regulators, or under an obligation to inform regulators, unless Government chose to regulate as a means of utilising accreditation as a quality assurance measure. This has been done previously, as has been the case with the dairy industry, and more recently with the Accident Compensation Corporation requiring radiology practices to be accredited in order to be able to claim subsidies from them.

26. Further, Telarc has no technical or other supervisory oversight powers unless a laboratory is already accredited. It is not, and never has been, Telarc's role to see whether obligations in contracts between health purchasers and providers are being performed, unless they have been incorporated as part of the accreditation criteria.
27. The major technical deficiencies I identified at the Gisborne Laboratory were:
  - (a) Lack of participation in external inter-laboratory proficiency testing with Royal College of Pathologists of Australasia ("RCPA"), or its equivalent.
  - (b) Lack of records indicating feedback on reading of slides and peer review of performance.
  - (c) Lack of on-going training through attendances at conferences and seminars.
  - (d) Generally run-down state of the laboratory and its equipment.
28. In my opinion, participation in external proficiency testing, or inter-laboratory comparisons, is the only way to determine clinical effectiveness, as diagnostic competence is based on on-going skill and experience. The RCPA enables pathologists to participate in inter-laboratory proficiency comparisons throughout Australasia for all testing modalities, which ensures diagnostic consistency through the ability of a particular pathologist to check their diagnosis against those of their peers and against reference diagnoses.
29. In my review of Gisborne Laboratories in October 1994, there were no records that I was made aware of that indicated that the cytology/histology department participated in RCPA inter-laboratory proficiency testing.
30. The report indicated that Gisborne Laboratories must participate in these inter-laboratory proficiency tests, either with RCPA or some similar organisation, before it would have any chance of obtaining accreditation.

31. While participation in inter-laboratory proficiency testing is relatively expensive, being approximately \$1,500 per discipline, and with some laboratories performing tests in 6 to 7 disciplines, it is crucial to ensure competence of pathology staff and the validity of test results.
32. While participation in inter-laboratory proficiency testing is not currently formally documented as being mandatory for accreditation, it has always in effect been mandatory as Telarc would never accredit a medical laboratory that could not demonstrate such participation. IANZ is, however, in the process of revising its code of laboratory practice which, when finalised, will formally endorse the need for participation in inter-laboratory proficiency testing as a mandatory requirement for accreditation, as medical laboratories must be able to demonstrate competence with their peers.
33. An important aspect of internal quality control is the ability to release apparently normal slides on the basis that a second person within the laboratory has re-screened a proportion of those slides and validated the test results. Gisborne Laboratories did not have such a second person. There was, therefore, no internal quality check, as well as there not being any opportunity for Dr Bottrill in the cytology/histology context to exchange ideas with another cytopathologist. In such a circumstance there is extreme pressure on the pathologist to get the test result right as there are no other means to intercept problems and carry out frequent and random checks on test results.
34. As far as I could ascertain during my visit, the “assistant” listed on the application for accreditation held no formal qualifications in cytology and was responsible only for staining the slides. The assistant did not participate in any screening of slides, and there was not much communication between Dr Bottrill and this person. It is imperative that, if a pathologist finds that a slide is not well prepared, he or she can go back and say they want it stained longer and so forth. This type of communication was not occurring at Gisborne Laboratories to the best of my knowledge from my visit in October 1994.

35. Attending conferences and continuing development courses is an important aspect for a pathologist to remain current and up-to-date. Normally, a laboratory will have records of the conferences attended by the pathologists. During my visit to Gisborne Laboratories, I was not shown, and did not see, any records of attendance at conferences or seminars, or certificates of attendance which are generally provided to attendees. Further, informal inquiries from pathologists at other medical laboratories left me with the impression that Dr Bottrill was relatively unknown to his peers.
36. The RCPA now organises its own continuing professional development programme which requires among other things all members to submit a dossier of attendances at meetings, conferences, seminars etc. These attendances qualify for a pre-determined number of points and all members are required to provide a formal electronic record of attendances at professional development courses to the RCPA which the College monitors.
37. In addition, it is vital to have access to current textbooks and scientific journals. My observation of Gisborne Laboratories was that the textbooks were out of date, and that there were only 2-3 scientific journals available.
38. My overall perception of Gisborne Laboratories was that there were many signs of the laboratory effectively being wound down and of limited capital expenditure. For example, the automated biochemistry and haematology analysers, which are critical items of test equipment in a medical laboratory, were of a type that I had not previously seen in other medical laboratories. My enquiries following this visit lead me to believe that the use of these types of analysers had been discontinued elsewhere in New Zealand.
39. This perception was also enhanced by the relative age of the equipment, including the laboratory microscope, and the fact that there were few, if any, records of annual maintenance of microscopes, etc. Also, the facilities were sub-optimal: for example the bench-tops were cracked and broken, and had not been repaired, and the exterior appearance of the building was in a poor state of repair.

40. Also, some of the testing procedures at Gisborne Laboratory followed earlier manual methods, which in many of the other laboratories I had visited had been superseded by more advanced automated methods.
41. Following the dispatch of the report to Gisborne Laboratories, there was no response received from them, and the files do not show any further contact with either Mr Reeve or Dr Bottrill.
42. In my professional opinion, I am very confident that accreditation would have ensured that checks were in place that are very likely to have prevented the under-reporting on cervical smear readings by Dr Bottrill at Gisborne Laboratories, as the competence and validity of test results would have been audited yearly, with a full audit being carried out every four years.

### **Medlab Gisborne**

43. I visited Gisborne Laboratories soon after it was taken over by Medlab Hamilton, and became Medlab Gisborne. There were still major gaps in compliance with accreditation requirements, and the improvements were not immediate, but were being addressed by Medlab Hamilton's quality manager, who spent long periods in Gisborne after the change-over in ownership.
44. Soon after the purchase by Medlab Hamilton, Telarc received a renewed inquiry for accreditation in respect of what was formerly known as Gisborne Laboratories.
45. Medlab Gisborne was able to obtain accreditation on 3 December 1997 as a result of the new owners, Medlab Hamilton, being a very large and well-resourced laboratory. Further, Medlab Hamilton was well aware of the requirements for accreditation as that laboratory had obtained accreditation on 9 September 1981. They were therefore able to provide the services of sound technical personnel to assist in preparing Medlab Gisborne to meet all of the accreditation criteria.

### **Gisborne Hospital Laboratory**

46. The laboratory at Gisborne Hospital obtained accreditation on 22 November 1990, including their cytology department.
47. Whilst Gisborne Hospital laboratory has been accredited for a reasonably long period, it has always been in the “borderline” category for one or more of its departments. In my professional opinion, Gisborne Hospital has never been particularly strong in any of its laboratory disciplines. I believe this is in part due to geographical isolation, with an insufficient catchment area to be able to retain the long-term services of good pathologists.
48. Dr Padwell was the pathologist at Gisborne Hospital for the majority of that period, and there were no concerns or indicators that led Telarc to believe the activities in the cytology/histology department were not sound. In particular, Dr Padwell did participate in the English equivalent of the RCPA inter-laboratory proficiency testing.
49. On 14 November 1999 the biochemistry department accreditation was suspended for disciplinary reasons, but the suspension has since been lifted. The accreditation of the cytology/histology department has since been rendered inoperative following the departure of its pathologist.

### **Laboratories Accredited During 1990 to 1996**

50. While accreditation can never be an absolute guarantee of competence, I believe it can be said with confidence that if a laboratory was accredited during the period 1990 to 1996 there is a reasonable expectation that laboratories were performing to acceptable standards. This is based on the fact that there is a rigorous process to be undertaken to obtain accreditation, once accredited the laboratory must participate in inter-laboratory proficiency testing such as that available from the RCPA, there are requirements for internal quality assurance, such as double reading of a percentage of slides, and there are minimum standards required in relation to technical performance, equipment, texts

and journals. Further, a laboratory would be required to show that it had actively followed up the histology results from colposcopies and biopsies, and this would be evaluated in the yearly audit.

51. Although the reading of cytology is ultimately the decision of 1 individual, it is my honest belief that the requirements for accreditation would have gone a long way to ensuring confidence in that individual's performance. Accreditation would not be able to ensure that a cytopathologist did not have an "off day", but it would pick up cumulative variations in performance or non-performance issues.

### **Draft National Quality and Services Standards for Medical Testing Laboratories**

52. Telarc has always consulted widely with public and professional organisations to ensure that the criteria for accreditation of medical laboratories reflect best industry practice. An example of this was in 1990 when Telarc modified the criteria following recommendations from the Cytology Advisory Liaison Committee.
53. In 1996, I was invited as a representative of Telarc, together with Dr Tony Barker, the Royal College of Pathologists of Australasia representative on the Telarc Medical Registration Advisory Committee (MEDRAC), which is now called MTPAC or Medical Testing Professional Advisory Committee, to participate in discussions with Sylvia Sax and Victoria Sinclair of the Southern Regional Health Authority. The objective was to develop additional quality criteria for medical laboratories. A document entitled "Draft National Quality and Service Standards for Medical Testing Laboratories" and known as the Draft Standard, resulted from these discussions. A copy of what I believe to be the latest official version of the Draft Standard, dated 29 May 1997, is annexed as **Exhibit GDW/IANZ/0005**.
54. I did, however, in March 2000 become aware that there might be another version of the Draft Standard in circulation. I requested a copy, which I received in May 2000, but I have not studied in detail any differences between the May 1997 and the June 1997 versions. Telarc are, however, assessing only against the May 1997 version of the Draft Standard produced as **GDW/IANZ/0005**.

55. I believe the topics to be covered in the Draft Standard were developed by the RHAs and Sylvia Sax. Tony Barker and I were first asked to comment on an already-existing draft rather than to formulate the Draft Standard from scratch, although I understand that we were asked to comment at a relatively early stage of its development. We suggested some amendments to the draft, and then comment was sought from numerous parties.
56. I am not aware whether any international standards were specifically considered in the preparation of the Draft Standard, although it is likely that some of Tony Barker's comments were based upon pre-existing documents developed either by the RCPA or the NCCLS. I am also not able to advise what, if any, input either the Ministry of Health or the RHAs may have had to ensure compliance with funding agreements. To the best of my knowledge this was not an issue that was raised in discussions with Telarc, and I certainly did not have any such discussions.
57. Earlier drafts of the Draft Standard were widely circulated to medical testing laboratories and other interested parties for comment, and Dr Tony Barker and I travelled to the five major centres around New Zealand with the Southern RHA staff, convening meetings for the purpose of gathering feedback in relation to the Draft Standard. This National Standard was, I understand, to be applied to medical laboratories by all of the four Regional Health Authorities.
58. The extensive consultation entered into in relation to the Draft Standard was largely at Telarc's suggestion. It was our belief that the Draft Standard needed to be well circulated for comment in order to gain broad industry acceptance and approval for its content and implementation. The RHAs were in agreement with the suggestion that the Draft Standard should be widely circulated for comment.
59. While it would have been relatively easy to shorten the consultative process, the likely result would have been a document that would not be readily accepted by the medical testing industry, and as such, there would have been only a poor attempt to comply with the requirements of the Standard.

60. The Draft Standard was not specifically written as a Cytology standard, but was written as a guideline for performance of medical laboratories in general. There was therefore no specific reference to Cytology requirements of the NCSP or of any other existing requirements for any medical testing disciplines.
61. The Draft Standard was not intended to include or cover existing standards for medical laboratories. The Draft Standard comprised very largely issues that were important to the RHAs at that time, which they did not believe were already specifically defined in existing standards. It was therefore always the intention, as I understand it, of both the RHAs and Telarc that while Telarc would assess its medical laboratories against the Draft Standard, in addition to its own criteria, the Draft Standard would remain a separate RHA document. It was agreed, however, that at some time in the future the requirements of the Draft Standard could be incorporated in revised Telarc criteria documents. No time frame was set for any such inclusion.
62. The Draft Standard contained a number of requirements of medical laboratories in order to satisfy the quality assurance requirements of the RHAs. Many of these had not previously been formally incorporated in Telarc criteria for accreditation. It was the intention of both the RHAs and Telarc that the Draft Standard would be incorporated in the Telarc criteria for accreditation. This final step never ultimately occurred, however, primarily, I understand, because the RCPA could not agree on several clauses relating to “Near Patient Testing” (which I understand is explained in the brief of evidence of Sylvia Sax).
63. Telarc would not have been averse to development of a separate standard for “Near Patient Testing”, as it was also relevant to Telarc’s Pharmacy accreditation programme. In fact, work had already been commenced on this standard. Regardless of whether “Near Patient Testing” was a separate standard or incorporated into the Draft Standard, however, it was Telarc’s view that it needed to be under at least the same level of control as testing performed within a medical laboratory.

64. Telarc strongly believed that the Draft Standard should apply equally to non-laboratory providers of “Near Patient Testing”. To exempt non-laboratory providers of “Near Patient Testing” from the requirements of any formal standard, or in fact from the accreditation process generally, would allow for the possibility of poorly trained and qualified staff performing critical tests on poorly managed equipment without formal quality control.
65. Notwithstanding the fact that the requirements of the Draft Standard were never formally incorporated in the Telarc criteria for accreditation, at a meeting of Telarc’s MTPAC in February 1997 the Draft Standard document was unanimously accepted for inclusion in the wider requirements of Telarc accreditation for medical laboratories. It was, however, resolved to leave the RHA requirements as a stand alone document rather than to incorporate its content within the Telarc published criteria for accreditation. An excerpt of the minutes of this meeting relating to the Draft Standards is annexed as **Exhibit GDW/IANZ/0006**. Many of the reports of Telarc assessments of medical testing laboratories issued since 1997 contain Corrective Action Requests raised against the requirements of the Draft Standard.
66. To my knowledge, the RHA Draft Standard document remains as a draft, and I am unaware of its formal publication. The requirements of the Draft Standard, dated 29 May 1997, however, continue to be assessed by Telarc (now IANZ) in its assessments of medical laboratories.
67. Telarc/IANZ would suspend an accredited medical laboratory if there were found to be substantial non-compliance with the Draft Standards.
68. The area of the Draft Standard where IANZ most frequently establishes poor compliance among many New Zealand medical laboratories relates to the requirement for pathologist input to laboratories. It is IANZ’s experience that many of the smaller medical testing laboratories are presently unable to demonstrate full compliance with the requirements of the Draft Standard in this area.

69. During discussions relating to the Draft Standards it was suggested that Telarc should undertake to notify the RHA where a medical laboratory was denied accreditation or where its accreditation was suspended.
70. Telarc/IANZ strongly resisted such an obligation being imposed on it because there were no formal arrangements agreed to by all of the parties. Therefore any such notification of the suspension or withdrawal of accreditation by Telarc would constitute a breach of the contractual relationship between Telarc and its clients, as well as representing a gross breach of confidence on behalf of Telarc. At present an assessor has access to all of the documents in a laboratory, including minutes, test costs, and so forth. Any breach of the contractual relationship or breach of confidence by Telarc could impede its ability to audit a medical laboratory and would ultimately lead to the erosion of trust between Telarc and its client laboratories, and accordingly valuable information needed for the success of the accreditation process would be withheld from Telarc.
71. Unless a laboratory is accredited, Telarc/IANZ has no “teeth” or ability to sanction a non-compliant laboratory. It was confirmed at a meeting of MEDRAC in February 1996 that it was the laboratory’s responsibility to inform the RHA regarding suspension of registration, and not that of Telarc. An excerpt of these minutes is produced as **Exhibit GDW/IANZ/0007**.
72. The resistance to notifying a suspension is also because a laboratory can be suspended for something as simple as non-payment of an invoice, which is no reflection on its competence.
73. If Telarc/IANZ were deemed to be the appropriate agency to notify the RHAs about the status of a medical laboratory relating to non-accreditation, suspension or withdrawal, such an obligation would need to be promulgated by regulation or statute. Further, it also does not preclude accreditation being a contractual requirement or prerequisite for reimbursement for laboratory services, and enforcement of that contractual requirement by the accountable government agency. Such enforcement, however, is not the role of Telarc/IANZ.

74. It should be stressed, however, that this does not preclude a government agency or any member of the public from contacting IANZ at any time and asking whether a particular medical laboratory is accredited or not. While they will not receive any details about the laboratory concerned, they will be told whether that laboratory is currently accredited or not.
75. Although the possibility of Telarc being nominated as the notifying agency was discussed between Sylvia Sax and Telarc during the preparation of the Draft National RHA Standards, I am personally unaware of any formal requests from any of the RHAs or any other party for information relating to the suspension of accreditation of medical laboratories.

### **Impact of Government Funding Constraints on Laboratory Standards**

76. In my role of visiting all medical laboratories, I have observed that they have increasingly become cash-strapped and are finding life financially difficult, particularly the hospital laboratories. Presently, laboratories in New Zealand are reimbursed at a much lower rate than laboratories in Australia.
77. In my view, the ramifications of this decreased funding has far-reaching consequences, which are only now beginning to show, and will, I believe, have a significant impact on standards, and therefore the validity of tests.
78. For example, I am noting that when a senior pathologist or technologist leaves a laboratory, that person is often replaced by a more junior, lesser-qualified and lower-cost person. There is therefore a loss of cumulative experience in the pathology sector, which represents a grave concern.
79. Much cyto-screening is carried out by Qualified Technical Assistants (“QTA’s”). While pathologists are now required to undertake continuing professional development by the RCPA, there is currently no mandatory requirement for QTA’s to maintain and upgrade their laboratory skills and they are not currently required to be

registered by any Board or have membership of any institution. This, therefore, could represent a problem area in an unaccredited laboratory, whereas if a Telarc/IANZ assessor found that a QTA had not been to a conference in the last five years there would automatically be a Corrective Action Request issued. The restriction of funding for attendance at conferences for QTAs does, however, represent an issue as it can be difficult to justify the expense when consideration is given to the loss of productive time, travel costs and the cost of attendance, all of which can represent several hundreds of dollars.

80. There are observable indicators of the restriction in funding to laboratories, such as less participation in conferences and continuing professional development seminars, out-of-date textbooks, reductions in the scientific journals subscribed to, and moves to reduce participation in inter-laboratory proficiency testing. Where these “slippages” occur, they will eventually lead to a lowering of standards and reduction of competency in the medical laboratories in New Zealand, which must raise serious questions about the validity of test results. This is particularly serious in anatomical testing, where the consequences of misdiagnoses may be potentially life threatening.

81. These factors are similar to those observed at Gisborne Laboratories during my visit in October 1994, and therefore are of serious concern.

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Graham Douglas Walker

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Date