

NORMAN PERLBERGER, ESQUIRE  
Pomerantz Perlberger & Lewis LLP  
Attorney ID #15742  
21 So. 12<sup>th</sup> Street, Suite 700  
Philadelphia, PA 19107  
(215)569-8866  
np@pomerantzperlberger.com

Attorney for Plaintiff

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IN THE COURT OF COMMON PLEAS  
OF MONTGOMERY COUNTY

NANCY CONRAD CLARK	:	CIVIL ACTION
10 N. Beech Street	:	
Fleetwood, PA 19522	:	
Plaintiff	:	
vs.	:	
FirstLab, a Subsidiary of	:	NO. 06-27461
FHC HEALTH SYSTEMS, INC.	:	
Welsh Commons	:	
1364 Welsh Road, Suite C-2	:	
North Wales, PA 19454-1913	:	
and	:	JURY TRIAL DEMANDED
QUEST DIAGNOSTICS, INC.,	:	
1290 Wall Street West	:	
Lyndhurst, NJ 07071	:	
and	:	
NATIONAL MEDICAL SERVICES, INC.	:	
d/b/a NMS LABS	:	
3701 Welsh Road	:	
Willow Grove, PA 19090	:	
Defendants	:	

**AMENDED COMPLAINT**

1. Plaintiff, NANCY CONRAD CLARK (“Clark”), is a citizen of the Commonwealth of Pennsylvania, residing therein at 10 N. Beech Street, Berks County, Fleetwood, PA 19522.

2. Defendant, FirstLab, a subsidiary of FHC HEALTH SYSTEMS, INC. (“FirstLab”), is a corporate entity with its principal place of business in the Commonwealth of Pennsylvania at Welsh Commons, 1364 Welsh Road, Suite C-2, North Wales, PA 19454-1913.

3. Defendant, QUEST DIAGNOSTICS, INC. (“Quest”), is a corporation with its principal place of business at 1290 Wall Street West, Lyndhurst, NJ 07071, and also having offices and doing business throughout the Montgomery County, Pennsylvania.

4. Defendant, NATIONAL MEDICAL SERVICES, INC. d/b/a NMS LABS (“NMS”) is a corporation with its principal place of business in the Commonwealth of Pennsylvania at 3701 Welsh Road, Willow Grove, PA 19090.

5. In 2005, Quest acquired LabOne, INC., dba Northwest Toxicology. All references to any of the three entities or fictitious names contained in this paragraph will hereafter be identified under the acquiring company’s name, “Quest”.

6. FirstLab is a third party administrator (“TPA”), specializing, inter alia, in the design, implementation, and management of drug and alcohol testing programs.

### **Operative Facts**

7. As a TPA, FirstLab contracts its services to various state and municipal agencies, as well as state licensure boards. At all relevant times pertinent to this action FirstLab provided TPA services to the State Board of Nursing of the Commonwealth of Pennsylvania. The Board administers, inter alia, the licensing privileges of registered nurses.

8. At all times relevant hereto, FirstLab also provided a Medical Review Officer (“MRO”) for the purpose of providing an independent review and opinion to the Board regarding whether the positive results of random alcohol testing upon a given nurse should be utilized for disciplinary purposes.

9. At all times relevant hereto, Quest and NMS provided to the Board the results of alcohol testing upon registered nurses as contracted through FirstLab.

10. Because of the sensitive nature of their positions with respect to patient care, registered nurses who have an admitted history of addiction, are required to enter into Voluntary Recovery Program Agreements (“VRP”), by which they agree to submit to random observed body fluid toxicology screening (“ROBS”) to document a drug-free condition in a known “zero-tolerance” environment.

11. Random drug screening is not a requirement for registered nurses in Pennsylvania, unless they have an admitted history of addiction and have voluntarily entered into a VRP Agreement as part of continued employment.

12. In July 2001, after admitting to Vicodin dependency, Nancy Clark signed a VRP Agreement with the Board submitting herself to future random testing.

13. There were no positive testing results or disciplinary actions taken between August 2001- May 2004, during which time Clark participated in the VRP and worked at Reading Hospital as a registered nurse.

14. All of Clark’s evaluations by her supervisors, including the last one on August 25, 2005, rated the quality of her work as “Outstanding”.

15. “EtG” stands for ethylglucuronide, a metabolite of alcohol, and was reported by Gregory Skipper, M.D. (“Dr. Skipper”) and Friedrich Wurst, M.D., in November 2002 at an international meeting of the American Medical Society, to provide proof of alcohol consumption as much as 5 days after drinking an alcoholic beverage, well after the alcohol itself had been eliminated from the body.

16. In 2003, because of these and other reportedly remarkable results (e.g., positive findings, confirmed by admissions by the tested individuals, after traditional urine tests had registered negative), EtG testing began in the United States.

17. FirstLab, NMS and Quest (through predecessors, Northwest Toxicology and LabOne) became leading proponents of EtG testing, and, starting in 2003, published statements and claims in their promotional materials, websites and articles that “EtG has emerged as the marker of choice for alcohol” and “that EtG is not detectable in the urine unless an alcoholic beverage has been consumed.” The test was touted as the “gold standard”.

18. In addition to such claims, starting in 2003, Defendants reprinted or quoted Dr. Skipper’s warning: “In the future, it will be negligent not to test for EtG when monitoring recovering alcoholics.”

19. Based on such unequivocally conclusive statements and claims, Pennsylvania instituted EtG testing and the State Board of Nursing became a signatory to a service contract with FirstLab as its TPA and MRO, which in turn engaged NMS and Quest as its testing lab facilities for the Commonwealth’s EtG testing programs.

20. By 2004, NMS and Quest (then Northwest Toxicology and LabOne) had established disparate “reporting limits” or “cutoffs” of 250 ng/mL and 100 ng/mL respectively, at or over which test results would be reported as “positive”.

21. Under the procedures established by the Board (similar to those adopted by other state and federal agencies), a positive finding would, upon the request of the tested professional, be reviewed by the MRO, before any disciplinary action would be taken. This function was performed by FirstLab.

22. On June 28, 2004 (less than three months prior to the expiration of her VRP Agreement), Clark submitted to a ROBS performed by NMS, and on the basis of a result of 370 ng/mL on an EtG test, she was found to be “Positive”, and thereby in violation of her VRP Agreement.

23. On December 6, 2004, the Board voted to suspend Clark’s license for three years but then stayed the suspension in favor of a term of probation of not less than 3 years, to end on December 6, 2007, subject to various terms and conditions.

24. Clark entered into a Consent Agreement, adopted by the Board on March 31, 2005, wherein the above terms and conditions were agreed upon, including continued VRP random testing. Said Agreement did not contain an admission that Clark had knowingly or voluntarily consumed alcohol at the time of the violation.

25. On May 2, 2005, Clark once again submitted to a ROBS this time performed by Quest (then Northwest Toxicology), and on the basis of a result of 780 ng/mL on an EtG test, she was found to be “Positive”, and thereby in violation of her Consent Agreement.

26. After a requested re-test which came back at 820 ng/mL (positive), Clark requested review by an MRO.

27. At all times relevant hereto, Clark denied having intentionally consumed alcohol.

28. FirstLab’s MRO, James Barnshaw, M.D., conducted the review (primarily by phone conference with Clark), without reviewing Clark’s recovery activities, talking to her family or work associates, or asking what her activities had been the day before, to determine if unknowing or incidental use could be identified.

29. Since her 2004 EtG tests, the cutoff has been raised from 250 to 500 ng/mL, which, if it had been the reporting limit in 2004, would have resulted in neither a “positive” EtG test result nor any disciplinary action.

30. On January 19, 2006, the Board vacated the stay of suspension of Clark's license, and an indefinite active suspension was imposed upon Clark, preventing her from employment as a nurse.

31. Insisting at all times that she had not consumed any alcoholic beverage and bewildered by her EtG results, after her suspension, Clark began her own review of the available medical literature and contacted Dr. Skipper.

32. Those efforts resulted in her discovery, among other things, that:

a. Many ordinary products, including the omnipresent Purell sanitizer used in hospitals throughout the country, contain ethanol;

b. The use or exposure to such products – known collectively as “incidental” or “involuntary” – could result in positive test results, since they all would metabolize as ethylglucuronide;

c. Cutoffs of 250 ng/mL and 500 ng/mL were arbitrary standards since incidental exposure to ethanol-containing products could show up at levels well above these levels;

d. The published state of scientific knowledge, going as far back as March 2004, included the information set forth in subparagraphs a-c above.

33. Dr. Skipper testified to all of the above at hearings held before the Bureau of Professional and Occupational Affairs' Hearing Examiner, C. Michael Weaver, on Clark's appeal from her suspension. Introduced in those proceedings was an Ethylglucuronide Advisory, issued by Dr. Skipper, on August 15, 2005, that levels under 1000 were problematic and that “a positive EtG is not necessarily proof of intentional alcoholic beverage consumption. Lower level positive tests are known to occur due to incidental exposure. The cutoff for possible incidental exposure vs. intentional use has not been accurately established.”

34. This Advisory has not deterred the \$4 billion-a-year industry, and the defendants (a) continue to publish material over the mails and internet wires that do not advise of such

warnings; (b) have not established a non arbitrary cutoff; and/or, (c) have not repudiated the test to the licensing agencies (such as the Board reviewing Clark's suspension).

35. At Clark's hearing, defendants Quest and NMS representatives testified supporting so called "positive" results that led to plaintiff's suspension, and opined that Clark had violated the Consent Agreement by drinking alcohol.

36. On cross-examination at Clark's hearing, these witnesses, all employed by the Defendants herein, admitted that the levels that Clark tested were in a "gray area" and that incidental exposure was known to the industry as generating positive EtG results.

37. FirstLab's MRO, Dr. Barnshaw, testified at Clark's hearing. His testimony demonstrates that his investigation had been cursory and that he did not have a grasp of the medical and scientific state of the art when he reviewed Clark's case. Nevertheless, he testified, against Clark's interest, that the positive test results were caused by her consumption of an alcoholic beverage.

38. While concluding there was a technical violation of the agreement since there was a positive test, the Hearing Examiner on July 31, 2006, held that the positive EtG finding of May 2005 was not proof that plaintiff had consumed an alcoholic beverage, and that "a sanction of active suspension of Respondent's license is not warranted due to her low screening results, and the controversy currently surrounding EtG testing."

39. The Hearing Examiner recommended by Proposed Order that Clark's Consent Agreement be reinstated, with the probation period as set forth therein ending on December 6, 2007. The Board filed its exception to have the Hearing Examiner's Proposed Order further reviewed pursuant to 1 Pa.Code §35.226(a)(2).

40. Plaintiff also appealed although the Hearing Officer's recommendation, if followed, would have reversed the active suspension, in order to clear from her record a second, albeit technical, violation.

41. On November 22, 2006 the State Board withdrew any prosecution asking for suspension or any further discipline against Plaintiff. Plaintiff now remains on her original probation that ends December 6, 2007 based only on the original June 2004 EtG test.

42. As of January 2007, the time of this Amended Complaint, although Plaintiff has sent out resumes, she has not been able to find a new nursing position.

43. On August 12, 2006, The Wall Street Journal published a front-page article, titled "A Test for Alcohol – And Its Flaws", with Clark's photograph and reporting on Clark's ordeal as a result of EtG testing.

44. Quoting Dr. Skipper, among others, the article includes:

"Little advertised, though, is that EtG can detect alcohol even in people who didn't drink. Any trace of alcohol may register, even that ingested or inhaled through food, medicine, personal-care products or hand sanitizer."

"The test 'can't distinguish between beer and Purell' hand sanitizer, says H. Westley Clark, director of the federal Substance Abuse and Mental Health Services Administration. . . 'When you're looking at loss of job, loss of child, loss of privileges, you want to make sure the test is right', he says..."

"Use of this screen has gotten ahead of the science,' says Gregory Skipper..."

45. Representatives of the testing labs, including Quest and NMS, continue to deny and challenge these warnings or advisories, insisting that the tests are accurate and reliable measurements, based on alleged scientific research. These denials include letters to the Wall Street Journal and telephonic interviews asserting the positions of the leading labs, Quest and NMS.

46. On September 28, 2006, SAMHSA, a federal agency that is part of the U.S. Department of Health and Human Resources, after hearings at which Clark delivered a statement regarding her ordeal, issued an Advisory, which on the first page contained a “grey box” warning, as follows:

“Currently, the use of an EtG test in determining abstinence lacks sufficient proven specificity for use as primary or sole evidence that an individual prohibited from drinking, in a criminal justice or a regulatory compliance context, has truly been drinking. Legal or disciplinary action based solely on a positive EtG, or other test discussed in this *Advisory* is inappropriate and scientifically unsupported at this time. These tests should currently be considered as potential valuable clinical tools, but their use in forensic settings is premature.”

47. Defendants have refused to follow the SAMSHA Advisory and continue to utilize arbitrary cutoffs, and support their “positive” findings to the Board (and other licensing and law enforcement agencies) in the face of disciplinary action against the tested individuals.

**COUNT I – FRAUDULENT MISREPRESENTATION**  
**(Plaintiff vs. All Defendants)**

48. Plaintiff incorporates by reference paragraphs 1-47 as if set forth fully hereunder.

49. Defendants, for reasons of maintaining the profits they have reaped in a \$4 Billion industry, have acted such as to filter out and ignore any oral statements and published findings, research, advisory warnings that draw into question the accuracy, efficacy and claimed foolproof results coming from the EtG test. This has been furthered by the following fraudulent activities:

a. Defendants have created web-sites, which direct prospective customers and the general public to linked articles, sales and promotional materials and alleged scientific studies, which falsely represented that positive EtG results can only come from drinking alcohol and that their cutoff levels create the marker and approved standard for reporting such positive results. These same misrepresentations have been made in brochures, advertisements and sponsored scientific studies;

b. Defendants have delivered sworn testimony in licensing hearings, including those involving Plaintiff herein, that the EtG positive results were only possible if the subject had been drinking alcohol. This bootstrapped advertising copy in their websites, brochures and other sales and promotional material, that: “EtG is not detectable in the urine unless an alcoholic beverage has been consumed.”

c. Defendants continued to carry on their websites outdated articles supporting their false and fraudulent claims, ignoring and refusing to substitute them for later studies that called for higher cutoffs; warnings of positive findings by reason of incidental exposure or consumption of alcohol-containing products, such as hand sanitizers and other commonly-used products by nurses and consumers; and, called for testing companies and employers utilizing these tests to understand that any results like Clark’s were in the “gray area” and not proof of drinking alcoholic beverages; and,

50. It is believed and averred that, in addition to the claims made above, discovery will establish that the misrepresentations and omissions of material facts were committed knowingly and wantonly in disregard of the lives and livelihoods of countless individuals, including the Plaintiff, through the suppression of information; the distortion of scientific research and studies; the false and misleading testimony and presentation of support for its EtG test to governmental bodies, professional societies and industrial organizations; false and deceptive advertising; false and deceptive published materials; the presentation of experts called to support their results in licensing hearings; the establishment of arbitrary and capricious cutoff levels; and, continued outdated advertising and sales materials in the face of research discrediting and/or raising serious questions about the validity of “positive” EtG results.

51. Said misrepresentations were calculated to maintain profitability and a captive market, despite the devastating consequences to the occupations and professions of hundreds of people who did not confess to drinking and who strenuously denied same.

52. Said misrepresentations and omissions of material facts were made recklessly, ignoring discrediting data, research and advice, and in total disregard of the impact on those positively-tested individuals, including Plaintiff, whose results were not probative of drinking alcohol, but which were used to suspend or revoke licenses needed for gainful employment in their chosen professions or occupations.

53. Continuation of this pattern by Defendants is also a continuation of damages to Plaintiff.

54. In submitting to her voluntary agreement to random testing through the Pennsylvania State Board of Nursing, Plaintiff Nancy Clark justifiably and reasonably relied that the testing, including the EtG test misrepresented by the Defendants, to which her urine would be subjected, was with valid tests that would not produce “false positives” that could be interpreted to indicate that she had consumed alcoholic beverages in violation of her agreement, and justifiably and reasonably relied that she would not be subjected to professional discipline as a result of an invalid and arbitrary test result, when she had in actuality adhered to her promise not to drink alcoholic beverages.

55. Plaintiff alleges that as a proximate cause of Defendants' fraudulent conduct, she has suffered, great, permanent and irreparable harm. These injuries include, but are not limited to: the active suspension of her license, further threat of future active suspension and/or revocation of her license, termination of her employment, bar to obtaining suitable future employment, loss of earnings and earning capacity, substantial counsel fees in defending herself before the Commonwealth, substantial and draining expenses associated with random EtG tests

and other evaluations, other pecuniary losses flowing directly and consequentially from her suspension, humiliation, damage to her reputation, insomnia, depression, anxiety and severe emotional and psychological distress, all or some of which are continuing in nature.

56. Defendants' conduct is alleged to be intentional, fraudulent, malicious and outrageous, entitling Plaintiff to punitive damages.

WHEREFORE, Plaintiff demands judgment against the Defendants for compensatory damages in an amount exceeding the jurisdictional limits requiring compulsory arbitration, and punitive damages, plus interest and costs.

**COUNT II – NEGLIGENT MISREPRESENTATION**  
**(Plaintiff vs. All Defendants)**

57. Plaintiff incorporates by reference paragraphs 1-56 as if set forth fully hereunder.

58. Defendants, their agents, employees and servants did negligently misrepresent material facts regarding their EtG testing including that:

a. The EtG test would unequivocally establish that a positive result indicated that the subject individual had consumed alcoholic beverages;

b. The cutoff or reporting limit, above which a "positive" result would occur was scientifically established after valid and reliable research;

c. The failure to conduct such a test would be negligence on the part of the employer;

d. The EtG test was the "gold standard" in ferreting out former alcoholics who were resuming prohibited alcoholic consumption in occupations requiring a "zero tolerance";

e. Employees who voluntarily agreed to random testing could rely on the accuracy of the EtG test in protecting them against false positives;

f. EtG is not detectable in the urine unless an alcoholic beverage has been consumed, thereby concealing that incidental or involuntary exposure or consumption of products containing alcohol could result in positive findings;

g. The continued re-evaluation and re-setting of cutoff limits were scientifically sound and reliable markers for detecting the prohibited activity of alcoholic beverage consumption;

h. Warnings or cautionary advisories issued by Dr. Skipper, SAMHSA and others -- that the cutoff levels were unreliable and arbitrary, and that incidental use could trigger positive results at or above the cutoffs – were insufficient to discredit the EtG test and its cutoff limits.

59. The misrepresentations by Defendants were made in false and misleading statements, oral and written, as well as through the omission of information known to discredit the EtG test to its customers, whose continued business supported a \$4 Billion industry.

60. Said misrepresentations and material omissions were calculated to increase their profits, retain the EtG test as the alleged “gold standard” in the detection of alcohol consumption by tested individuals, and to suppress and attempt to refute the mounting scientific, medical and governmental advisories, warnings and published reports, and the misrepresentations were malicious and in total disregard of plaintiff, who subjected herself to the screening program, in justifiable reliance on the validity and truthful reporting and interpreting of the administered tests, aimed at supporting her abstinence in order to maintain her professional license and occupation.

61. Said misrepresentations and omissions of material facts were made recklessly, ignoring discrediting data, research and advice, and in total disregard of the impact on those positively-tested individuals, including Plaintiff, whose results were not probative of drinking alcohol, but which were used to suspend or revoke licenses needed for gainful employment in their chosen professions or occupations.

62. In submitting to her voluntary agreement to random testing through the Pennsylvania State Board of Nursing, Plaintiff Nancy Clark justifiably and reasonably relied that the testing, including the EtG test misrepresented by the Defendants, to which her urine would be

subjected, was with valid tests that would not produce “false positives” that could be interpreted to indicate that she had consumed alcoholic beverages in violation of her agreement, and justifiably and reasonably relied that she would not be subjected to professional discipline as a result of an invalid and arbitrary test result, when she had in actuality adhered to her promise not to drink alcoholic beverages.

63. As a result of Defendants’ negligent misrepresentations, Plaintiff suffered the active suspension of her license, further threat of future active suspension and/or revocation of her license, termination of her employment, bar to obtaining suitable future employment, loss of earnings and earning capacity, substantial counsel fees in defending herself before the Commonwealth, substantial and draining expenses associated with random EtG tests and other evaluations, other pecuniary losses flowing directly and consequentially from her suspension, humiliation, damage to her reputation, insomnia, depression, anxiety and severe emotional and psychological distress, all or some of which are continuing in nature.

64. Said misrepresentations were, therefore, outrageous in nature, entitling Plaintiff to both compensatory and punitive damages.

WHEREFORE, Plaintiff demands judgment against the Defendants for compensatory damages in an amount exceeding the jurisdictional limits requiring compulsory arbitration, and punitive damages, plus interest and costs.

**COUNT III – NEGLIGENCE**  
**(Plaintiff vs. All Defendants)**

65. Plaintiff incorporates by reference paragraphs 1-64 as if set forth fully hereunder.

66. Defendants, by promoting, advertising, marketing, selling, and/or contracting with the licensing board, and/or designing, implementing, and managing the drug and alcohol testing program, and/or collecting the urine samples and/or utilizing the EtG test to allegedly establish

that the plaintiff consumed an alcoholic beverage, had a duty to use a reasonable degree of care to avoid erroneous test results.

67. Plaintiff, as a nurse, was an intended test subject and Defendants knew that her license and occupation would be in jeopardy if she tested positive.

68. Plaintiff by entering into voluntary screening program, both for rehabilitative and occupational reasons, relied on the validity of the tests to which she subjected herself – with the goal that they could provide laboratory evidence of her abstinence.

69. Because of the obvious foreseeable serious and devastating consequences of reporting that the results were positive (within cutoffs established by the Defendants), Defendants had to exercise duty to use a reasonable degree of care to avoid erroneous test results to the foreseeable test subjects, including the plaintiff.

70. Instead, Defendants acted negligently and recklessly in:

- a. Marketing their tests without conducting adequate scientific or medical studies;
- b. Establishing cutoffs over which test results would be reported as “positive” that were arbitrary and scientifically unreliable and invalid;
- c. Promoting the EtG test with unsupported and false statements that a positive EtG test would unequivocally establish that the subject individual had consumed alcoholic beverages;
- d. Publishing warnings that the failure to conduct such a test would be negligence on the part of an employer or licensing board;
- e. Falsely asserting that the EtG test was the “gold standard” in ferreting out former alcoholics or drug users who were resuming or beginning to engage in prohibited alcoholic consumption in occupations requiring a “zero tolerance”;
- f. Falsely asserting that EtG is not detectable in the urine unless an alcoholic beverage has been consumed, thereby concealing that incidental or involuntary exposure or consumption of products containing alcohol could result in positive findings;

- g. Failing and refusing to re-evaluate and re-set cutoff limits at levels that were scientifically sound and reliable markers for detecting the prohibited activity of alcoholic beverage consumption, and excluding other causes for their results;
- h. Failing to heed the warnings or cautionary advisories issued by Dr. Skipper, SAHMSA and others – that the cutoff levels were unreliable and arbitrary, and that incidental use could trigger positive results at levels at or above the cutoffs – and, instead, denying publicly and maintaining the warnings were insufficient to discredit the EtG test and its cutoff limits;
- i. Bootstrapping the alleged positive evidence of alcohol consumption with the incompetent, inadequate and cursory review by FirstLab’s MRO, whose duty to the Plaintiff was to protect her from false accusations, and to provide licensing boards and employers with: 1) either a conclusion that cautioned against disciplinary or other punitive action in the face of a “positive” EtG test, or 2) concluding that other factors or causes were identified to account for the positive results; and,
- j. Failing to protect the plaintiff from foreseeable substantial harm in the form of disciplinary and punitive measures, when their EtG test systems were employed and relied upon for their accuracy and reliability.

71. As a direct and proximate result of the Defendants’ negligence Plaintiff suffered the active suspension of her license, further threat of future active suspension and/or revocation of her license, termination of her employment, bar to obtaining suitable future employment, loss of earnings and earning capacity, substantial counsel fees in defending herself before the Commonwealth, substantial and draining expenses associated with random EtG tests and other evaluations, other pecuniary losses flowing directly and consequentially from her suspension, humiliation, damage to her reputation, insomnia, depression, anxiety and severe emotional and psychological distress, all or some of which are continuing in nature.

72. The aforesaid negligence on the part of the Defendants was outrageous in nature and, therefore, entitles the Plaintiff to both compensatory and punitive damages.

WHEREFORE, Plaintiff demands judgment against the Defendants for compensatory damages in an amount exceeding the jurisdictional limits requiring compulsory arbitration, and punitive damages, plus interest and costs.

**COUNT IV – BREACH OF FIDUCIARY DUTY**  
**(Plaintiff vs. FirstLab)**

73. Plaintiff incorporates by reference paragraphs 1-72 as if set forth fully hereunder.

74. At all times material hereto, Dr. Barnshaw was the Chief Medical Review Officer (“MRO”) for FirstLab.

75. By federal and state law, the test results coming from Quest and NMS are contracted by a third party administrator (“TPA”) with the Commonwealth’s Board of Nursing, which in this case was FirstLab.

76. Implementing regulations require that when test results are reviewed by an MRO, it be a licensed physician having no connection to Quest or NMS.

77. FirstLab, therefore, acted through its then agent, Dr. Barnshaw, to perform MRO activity for various governmental and defense contractors, Fortune 500 companies, airline consortia and licensing boards.

78. In the case of registered nurses licensed in Pennsylvania, a TPA, through its MRO, has a fiduciary duty to the nurses who enter into VRP and Consent Agreements to undergo random drug and alcohol testing to insure that they have not resumed drinking alcohol, because the nurse’s license and reputation are dependent on the findings made by the MRO.

79. FirstLab, through its MRO, is the sophisticated intermediary, purportedly acting in the dual capacity of: (1) protecting patients from nurses practicing under the influence of alcohol and (2) insuring that nurses are not wrongly disciplined when they deny consumption of alcoholic beverages.

80. Plaintiff contracted with FirstLab for their MRO service concerning her May 2005 positive EtG test result. It was an oral agreement for which Plaintiff paid fifty dollars to FirstLab.

81. FirstLab (through Dr. Barnshaw) owed Clark, who relied and trusted that FirstLab, in its capacity as MRO, would fairly and appropriately use its power over her license, a fiduciary duty to discharge its contractual and professional responsibilities with due care, with requisite skill and training, and with the expertise necessary to render opinions to the Board of Nursing when her licensing privileges were at risk.

82. There was a substantial disparity in the position of Clark and FirstLab relative to FirstLab's capacity as MRO concerning how the EtG test would be interpreted, with FirstLab having overmastering dominance as to that decision with its substantial foreseeable harm to Clark.

83. Plaintiff is unaware as to whether the contract between the Board and FirstLab was written or oral and if written that contract is inaccessible to Plaintiff.

84. It was the responsibility of the FirstLab's MRO, in reviewing whether the EtG test result was due to Plaintiff drinking an alcoholic beverage, to interview Clark, her superiors and co-workers, family and counselors; determine any history of alcohol abuse, review her abstinence, rehabilitation and work record; and, explore alternate causes for the positive test result as well as to have adequate knowledge concerning EtG to make a responsible determination.

85. FirstLab through its employee and agent Dr. Barnshaw failed to discharge its duty to Clark in the conduct of his review, his level of knowledge concerning EtG and his ultimate report to the Board.

86. Dr. Barnshaw testified by telephone at the Clark hearings on the same day, Quest and NMS expert witnesses testified, who admitted on cross-examination, inter alia, that levels like Clark's were in the "gray area", incidental non-beverage use could result in positive results, and the applicable cutoff limits were not scientifically established.

87. Despite his incomplete and inadequate MRO review of Clark's case, Dr. Barnshaw maintained under oath that Clark had been drinking and that his report of same to the Board was appropriate.

88. FirstLab knew or should have known that the testimony, published data, advertising, sales promotional material, websites, and other oral and written communications, were false, misleading and detrimental to Plaintiff.

89. FirstLab knew that MRO confirmation that Clark had been drinking alcohol would result in disciplinary action, including suspension of her license.

90. In ignoring reports, advisory warnings, published articles and other communications that discredited its own representations, and in rendering an opinion to the Board that Clark had been drinking, FirstLab is liable to Clark for breach of fiduciary duty.

91. As a result of FirstLab's breach of fiduciary duty, Plaintiff suffered the active suspension of her license, further threat of future active suspension and/or revocation of her license, termination of her employment, bar to obtaining suitable future employment, loss of earnings and earning capacity, substantial counsel fees in defending herself before the Commonwealth, substantial and draining expenses associated with random EtG tests and other evaluations, other pecuniary losses flowing directly and consequentially from her suspension, humiliation, damage to her reputation, insomnia, depression, anxiety and severe emotional and psychological distress, all or some of which are continuing in nature.

92. FirstLab's breach of its fiduciary duties to Plaintiff is alleged to be intentional, fraudulent, malicious and outrageous, entitling Plaintiff to punitive damages.

WHEREFORE, Plaintiff demands judgment against the Defendants for compensatory damages in an amount exceeding the jurisdictional limits requiring compulsory arbitration, and punitive damages, plus interest and costs.

**COUNT V – PRODUCTS LIABILITY**  
**(Plaintiff vs. All Defendants)**

93. Plaintiff incorporates by reference the allegations contained in paragraphs 1-92 above, as if set forth fully hereunder.

94. The EtG testing systems, developed, promoted, marketed, sold and administered to and for the use of the state licensing board in the stream of commerce, constitute products placed into the stream of interstate commerce.

95. Said products are defective in their establishment of artificial and scientifically unsound cutoff levels and then marketed and advertised as described in the foregoing incorporated paragraphs, such that the licensing boards and the ultimate end users, including plaintiff who purchased the EtG tests did not obtain the products' intended uses.

96. Defendants are strictly liable for damages to Plaintiff for the sale of products, defective in their design, marketing and false advertising.

97. As a proximate cause of Defendants' strict liability for the sale of their defective products, Plaintiff suffered the active suspension of her license, further threat of future active suspension and/or revocation of her license, termination of her employment, bar to obtaining suitable future employment, loss of earnings and earning capacity, substantial counsel fees in defending herself before the Commonwealth, substantial and draining expenses associated with random EtG tests and other evaluations, other pecuniary losses flowing directly and

consequentially from her suspension, humiliation, damage to her reputation, insomnia, depression, anxiety and severe emotional and psychological distress, all or some of which are continuing in nature.

98. It is believed and therefore averred that the aforesaid sale and marketing of the product by the Defendants was with knowledge that it was defective for its promoted use and/or was with reckless indifference, and was outrageous in nature, therefore, entitling the Plaintiff to both compensatory and punitive damages.

WHEREFORE, Plaintiff demands judgment against the Defendants for compensatory damages in an amount exceeding the jurisdictional limits requiring compulsory arbitration, and punitive damages, plus interest and costs.

**COUNT VI – BREACH OF WARRANTY FOR INTENDED USE**  
**(Plaintiff vs. All Defendants)**

99. Plaintiff incorporates by reference paragraphs 1-98 as if set forth fully hereunder.

100. Defendants have marketed the EtG test for the intended use, inter alia, of identifying individuals engaged in certain professions and occupations who have consumed alcoholic beverages, thereby exposing others to potential harm in the discharge of their duties.

101. As alleged above, Defendants have warranted that the positive results above their cutoff levels, and in the case of the TPA through confirmation by its MRO, could be relied upon by licensing agencies such as the Board in disciplining individuals, such as the Plaintiff.

102. Defendants have represented and warranted that the EtG test is the most reliable – gold standard – product on the market and that it can give to contracting agencies reliable results detecting the consumption of alcoholic beverages by individuals who have entered into formal agreements not to drink any such beverages in order to maintain their licensure and right to work in their chosen professions.

103. In advertising, marketing, promoting and selling their products, under the above false promises and representations that they could be used effectively and accurately, without attendant economic and non-economic injuries, Defendants breached the warranty of merchantability and their contractual obligations to sell products for their intended use.

104. Said warranties to their products and services for the intended use for which they are marketed are untenable and incapable of reliable usage, thereby constituting breach of the warranties for intended use that Defendants' products and services were advertised, promoted, merchandised and sold.

105. This breach is actionable and entitles Plaintiff as an intended third party beneficiary who paid for the testing, to direct and consequential damages, including but not limited to: past and future out-of-pocket costs, lost wages or income and loss of earning capacity. Such warranties were either oral or made in writings to the licensing board and or their agents that are inaccessible to Plaintiff.

106. As a result of Defendants' breaches, Plaintiff has directly and consequently suffered the active suspension of her license, further threat of future active suspension and/or revocation of her license, termination of her employment, bar to obtaining suitable future employment, loss of earnings and earning capacity, substantial counsel fees in defending herself before the Commonwealth, substantial and draining expenses associated with random EtG tests and other evaluations, other pecuniary losses flowing directly and consequentially from her suspension.

WHEREFORE, Plaintiff demands judgment against the Defendants for compensatory damages in an amount exceeding the jurisdictional limits requiring compulsory arbitration, plus interest and costs.

**COUNT VII – VIOLATION OF PENNSYLVANIA UNFAIR TRADE  
PRACTICES AND CONSUMER PROTECTION LAW  
(Plaintiff vs. All Defendants)**

107. Plaintiff incorporates by reference paragraphs 1-106 as if set forth fully hereunder.

108. The actions of the Defendants as described above are in violation of 73 P.S. §§ 201-1 - 201-9.3, specifically § 201-4 v. (“representing that goods or services have ...characteristics...uses, benefits...that they do not have...”), § 201-4 vii. (“Representing that goods or services are of a particular standard, quality or grade...if they are of another”) and § 201-4 xxii. (“Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding.”)

109. Plaintiff purchased the defendants EtG test for personal purposes under the act and is therefore entitled to an award of up to three times her actual damages for monetary loss as a result of the active suspension of her license, further threat of future active suspension and/or revocation of her license, termination of her employment, bar to obtaining suitable future employment, loss of earnings and earning capacity, substantial counsel fees in defending herself before the Commonwealth, substantial and draining expenses associated with random EtG tests and other evaluations, other pecuniary losses flowing directly and consequentially from her suspension.

WHEREFORE, Plaintiff demands judgment under 73 P.S. §§ 201-1 - 201-9.3 against the Defendants for compensatory damages in an amount exceeding the jurisdictional limits requiring compulsory arbitration, plus attorney fees, interest and costs and other relief this Honorable Court deems necessary or proper.

POMERANTZ PERLBERGER & LEWIS LLP

BY: \_\_\_\_\_  
Norman Perlberger, Esquire  
Attorney for Plaintiff