CLAIMS

What is claimed is:

1. A method of reducing background noise and improving the signal to noise ratio in integrity testing to disposition at least one membrane filter comprising:

performing a gas-liquid diffusion analysis on the membrane filter to obtain a value for the membrane filter;

identifying whether value for the membrane filter is an outlier compared to an initial fixed cutoff during the gas-liquid diffusion analysis, wherein the initial fixed cutoff comprises an upper specification limit and a lower specification limit and is used to identify rejects;

normalizing a value based on at least one property or operating condition of a sub-population of membrane filters that causes variation in the gas-liquid diffusion analysis, if the membrane filter is not the outlier to the initial fixed cutoff;

identifying whether the normalized value of the membrane filter is an outlier compared to a secondary statistical cutoff, wherein the secondary statistical cutoff comprises an upper specification limit and a lower specification limit based on the values from previous gas-liquid diffusion analyses of a plurality of membrane filters; and

dispositioning the membrane filter as integral or failing, wherein a membrane filter that is an outlier to the initial cutoff or the secondary cutoff is dispositioned as failing, and a membrane filter that is not an outlier to the initial cutoff or the secondary cutoff is dispositioned as integral.

2. The method of claim 1, wherein the gas-liquid diffusion method is air-water.

3. The method of claim 1 or 2, wherein the at least one property or operating condition is chosen from the group consisting of lot, equipment test position, water temperature, air temperature, and pressure.

4. The method of claim 1 or 2, wherein the values of at least two properties and/or operating conditions are normalized.

5. The method of claim 1 or 2, further comprising normalizing the pressure of the more than one membrane filter.

6. The method of claim 1 or 2, further comprising detecting at least one defect in more than one membrane filter.

7. The method of claims 1 or 2, wherein the membrane filter is a 10-inch sterilizing grade filter.

8. The method of claim 6, wherein the at least one defect is selected from the range consisting of between 4 µm and 9 µm.

9. The method of claim 8, wherein the defect is greater than 4 µm.

10. The method of claim 6, wherein the defect is selected from the group consisting of 4 µm, 5 µm, 6 µm, 7 µm, 8 µm, and 9 µm.

11. The method of claim 1, wherein the initial upper cutoff maintains at least a 5% safety factor from end-user diffusion specification criteria.

12. The method of claim 1, wherein the initial upper cutoff maintains at least a 5% safety factor from Quality Control (QC) lot release diffusion criteria.

13. The method of any one of claims 11 and 12, wherein the initial upper cutoff maintains a safety factor selected from the range consisting of between 5% to 15% from end-user diffusion specification criteria or Quality Control (QC) lot release diffusion criteria.

14. The method of claim 13, wherein the initial upper cutoff maintains a safety factor selected from the group consisting of 5 %, 6 %, 7 %, 8 %, 9 %, 10 %, 11 %, 12 %, 13 %, 14 %, and 15 %.

15. The method of claim 1 or 2, wherein the plurality is a statistically significant number of membrane filters.

16. The method of claim 1 or 2, wherein the membrane filter and the plurality of membrane filters are the same type of filtration device.

17. The method of claim 16, wherein the filtration device is selected from the group consisting of: sterilizing grade filters, virus filters, clarification filters, and ultrafiltration filters.

18. The method of claim 1 or 2, wherein the secondary statistical cutoff is established by setting the upper statistical limit to between 2 and 5 standard deviations above the normalized median of the values.

19. The method of claim 18, wherein the secondary statistical cutoff is established by setting the upper statistical limit to 2, 3, 4, and 5 standard deviations above the normalized median of the values.

20. The method of claim 1 or 2, wherein the secondary statistical cutoff is established by setting the lower statistical limit to between 4 and 6 standard deviations below the normalized median of the values.

21. The method of claim 20, wherein the secondary statistical cutoff is established by setting the upper statistical limit to 2, 3, 4, and 5 standard deviations above the normalized median of the values.