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Stability Study for Reagecon pH Buffers

Introduction:

Reagecon's pH buffer standards are directly traceable to the IUPAC pH scale by an unbroken chain of traceability. Reagecon achieve this traceability through a series of comparisons, with the key reference materials being Standard Reference Materials (SRMs) manufactured by NIST.

For proof of traceability, all of these comparisons must be made in a technically - valid manner and the accuracy of each step must be quantified by calculating the associated Uncertainty of Measurement. Reagecon's pH buffer standards meet the ISO definition of traceability: "The ability to relate measurements back to a stated reference (usually an international standard) through an unbroken chain of comparisons, each having stated uncertainties of measurement." Reagecon's traceability claims are guaranteed by our accreditation to ISO 17025.

In addition to the certification to ISO 9001:2008, Reagecon's pH analysis is also accredited to ISO 17025 – "General requirements for the competence of testing and calibration laboratories". Reagecon's accreditation to ISO 17025 gives independent proof of three key areas:

- Our pH analysis is technically valid and is carried out in a thoroughly controlled manner by highly - qualified staff.
- Our claims over the accuracy of our pH analysis are valid and we have properly quantified our accuracy in our Uncertainty of Measurement calculations.
- Our pH analysis is traceable to NIST SRMs. It is important to note that NIST do not police claims of traceability to their SRMs. Any manufacturer of pH buffers can claim that their

buffers are traceable to NIST, but only manufacturers that are accredited to ISO17025 have independent proof of their traceability.

Reagecon's accreditation is indicated by the Irish National Accreditation Board (INAB) logo on our Certificates of Analysis for pH Buffers. Accreditation by INAB and all other accreditation boards validated to accredit ISO 17025 are mutually recognised as being directly equivalent.

Reagecon's pH buffers have been specially formulated to ensure their stability. The packaging bottles that we use have also been selected and tested to provide maximum stability. We have conducted stability trials on both freshly-opened and part-full bottles of our pH buffers to validate their shelf-life - examples are given in the graph above. This demonstrates that Reagecon's pH buffers will stay within their specification limits up to the stated expiry date regardless of when the bottle was first opened (provided that the pH buffer is stored in accordance with good laboratory practice).

This stability trial was conducted at:

Testing Temperature: 25°C

Storage Temperature: 10°C to 25°C

Head-space in the bottle: 20%

Bottle Material: HDPE

Duration after opening for working bottles: approximately 3 minutes each time

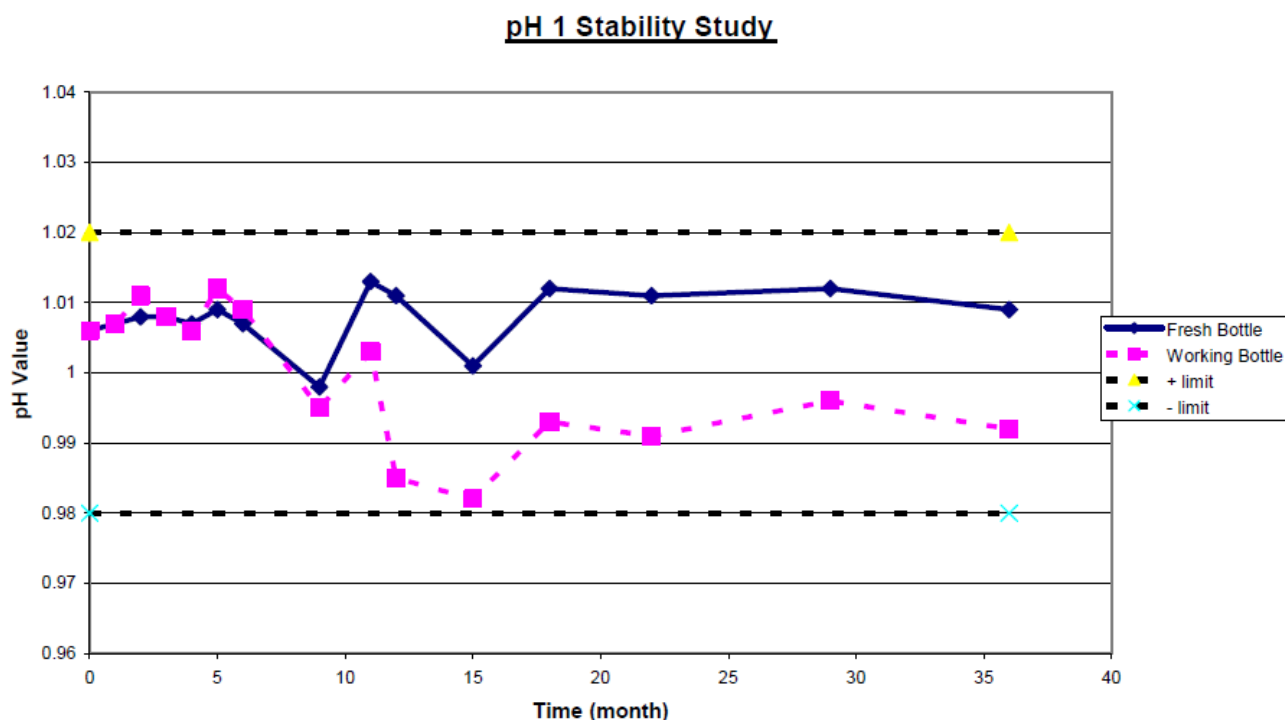
Time intervals of testing: 3 months

Humidity: 45%--75%

Operator: Leo Geary

Most of Reagecon's pH buffers have an expiry date of either 2 years or 3 years from the date of manufacture. This means that our pH buffers' expiry dates are an absolute value and they have a long "Active Life". We do not quote a short usage period after opening the bottle and there is no need to record by hand an "Opened on date" and a "Use by date". With Reagecon's pH buffers you just open the bottle and use the contents - with other manufacturers' pH buffers you need to record these extra dates and may need to dispose of most of the contents of the bottle at the end of its short "Active Life".

Summary of stability data for Reagecon pH buffers



Product No: 1010525

Nominal Value: pH1.00@25 °C

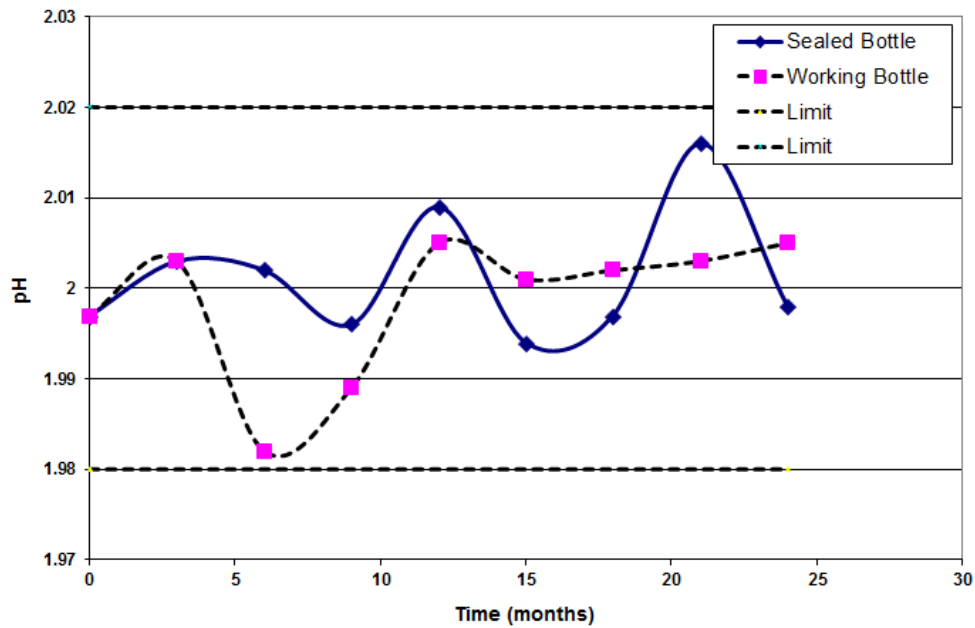
pH Measurement:

The test Method for 1010525 used was TPPHB. Measured with a combination glass electrode after multiple point calibration with reference materials. It is certified traceable to the following National Institute of Standards and Technology (USA), SRM 189c Potassium Tetraoxalate and SRM 185h Potassium Hydrogen Phthalate. The uncertainty of measurement has been calculated not to exceed $\pm 0.02\text{pH}$ at 95% confidence level, i.e. coverage factor $k = 2$.

Buffer Substance:

Hydrochloric Acid, Potassium Chloride.

pH 2.00 Stability Study



Product No: 1020525

Nominal Value: pH2.00@25 °C

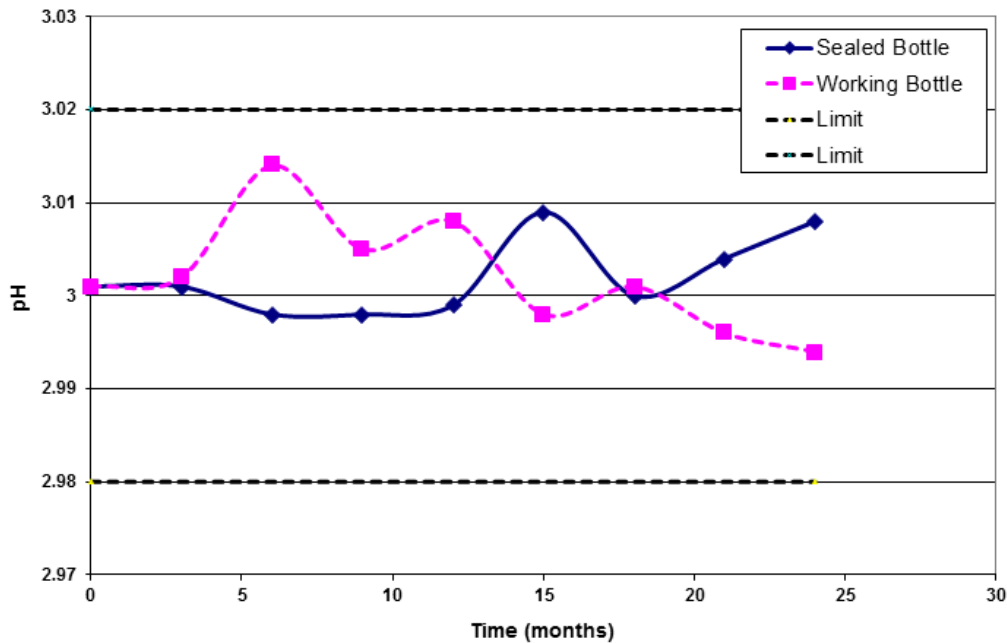
pH Measurement:

The test Method for 1020525 used was TPPHB. Measured with a combination glass electrode after multiple point calibration with reference materials. It is certified traceable to the following National Institute of Standards and Technology (USA), SRM 189c Potassium Tetraoxalate and SRM 185i Potassium Hydrogen Phthalate. The uncertainty of measurement has been calculated not to exceed $\pm 0.02\text{pH}$ at 95% confidence level, i.e. coverage factor $k = 2$.

Buffer Substance:

Glycine, Hydrochloric Acid, Sodium chloride.

pH 3.00 Stability Study



Product No: 1030525

Nominal Value: pH3.00@25 °C

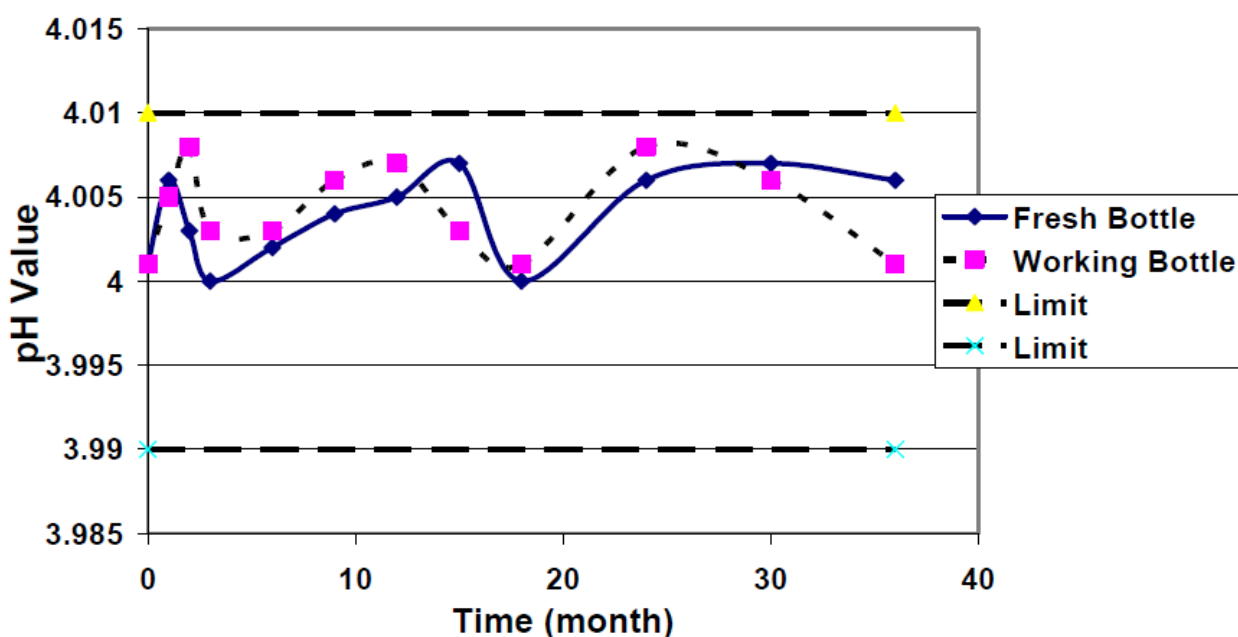
pH Measurement:

The test Method for 1030525 used was TPPHB. Measured with a combination glass electrode after multiple point calibration with reference materials. It is certified traceable to the following National Institute of Standards and Technology (USA), SRM 189c Potassium Tetraoxalate and SRM 185h Potassium Hydrogen Phthalate. The uncertainty of measurement has been calculated not to exceed $\pm 0.02\text{pH}$ at 95% confidence level, i.e. coverage factor $k = 2$.

Buffer Substance:

Potassium Hydrogen Phthalate, Hydrochloric Acid.

pH 4 Stability Study



Product No: 1040525 & 1040525CTT

Nominal Value: pH4.00@25 °C

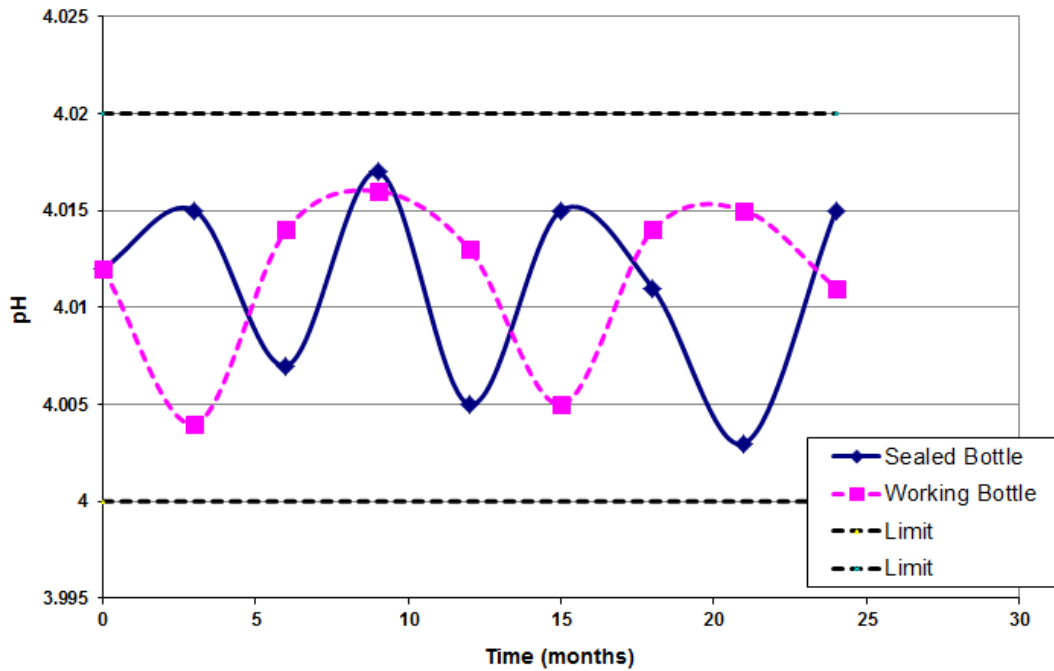
pH Measurement:

The test Method for 1040525 used was TPPHB. Measured with a combination glass electrode after multiple point calibration with reference materials. It is certified traceable to the following National Institute of Standards and Technology (USA), SRM 185h Potassium Hydrogen Phthalate, SRM 186-I-g Potassium Dihydrogen Phosphate and SRM 186-II-g Disodium Hydrogen Phosphate. The uncertainty of measurement has been calculated not to exceed $\pm 0.01\text{pH}$ at 95% confidence level, i.e. coverage factor $k=2$.

Buffer Substance:

Potassium Hydrogen Phthalate.

pH 4.01 Stability Study



Product No: 10401255CTT

Nominal Value: pH4.01 @25 °C

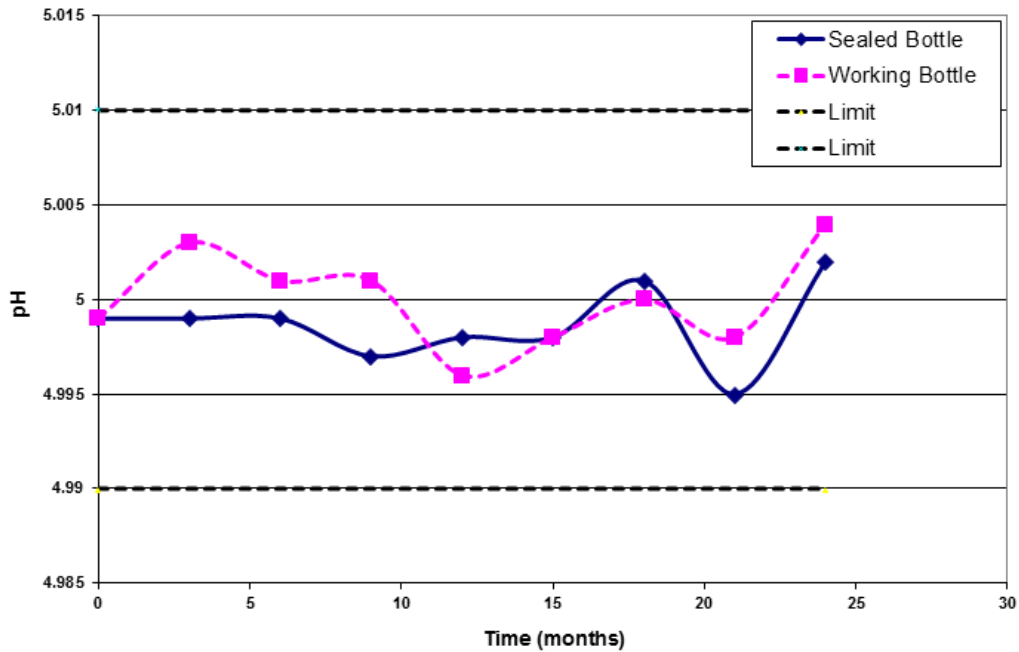
pH Measurement:

The test Method for 10401255CTT used was TPPHB. Measured with a combination glass electrode after multiple point calibration with reference materials. It is certified traceable to the following National Institute of Standards and Technology (USA), SRM 185i Potassium Hydrogen Phthalate, SRM 186-I-g Potassium Dihydrogen Phosphate and SRM 186-II-g Disodium Hydrogen Phosphate. The uncertainty of measurement has been calculated not to exceed $\pm 0.01\text{pH}$ at 95% confidence level, i.e. coverage factor $k = 2$.

Buffer Substance:

Potassium Hydrogen Phthalate.

pH 5.00 Stability Study



Product No: 1050525

Nominal Value: pH5.00 @25 °C

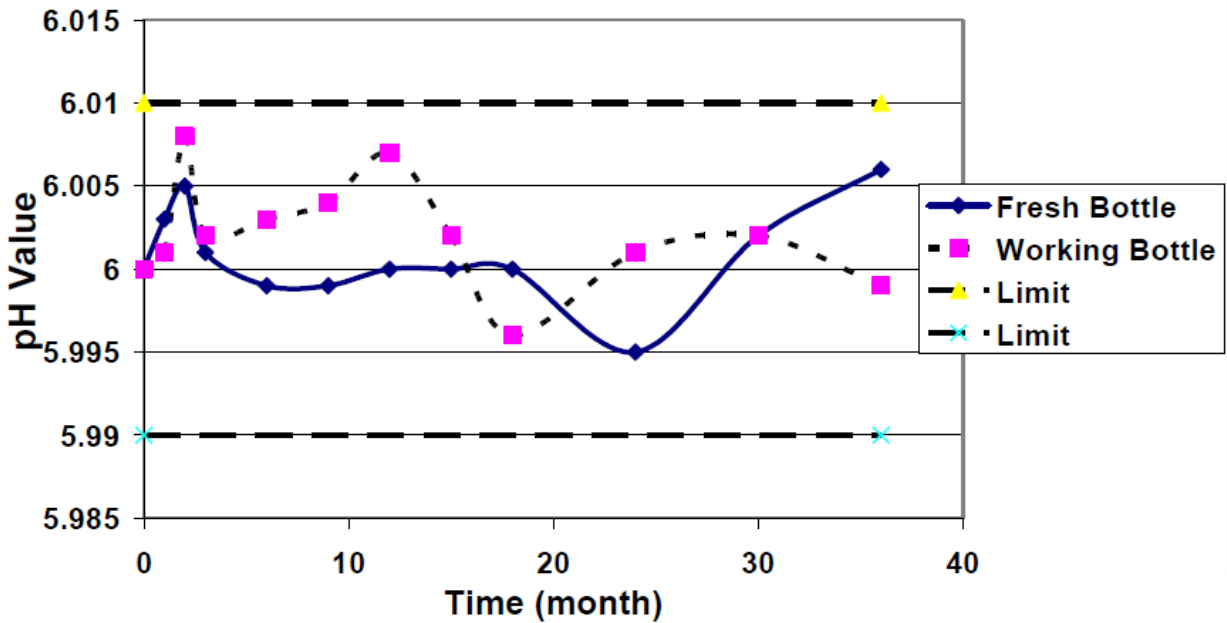
pH Measurement:

The test Method for 1050525 used was TPPHB. Measured with a combination glass electrode after multiple point calibration with reference materials. It is certified traceable to the following National Institute of Standards and Technology (USA), SRM 185h Potassium Hydrogen Phthalate, SRM 186-I-g Potassium Dihydrogen Phosphate and SRM 186-II-g Disodium Hydrogen Phosphate. The uncertainty of measurement has been calculated not to exceed $\pm 0.01\text{pH}$ at 95% confidence level, i.e. coverage factor $k = 2$.

Buffer Substance:

Potassium Hydrogen Phthalate, 1M Sodium Hydroxide.

pH 6 Stability Study



Product No: 1060525

Nominal Value: pH6.00 @25 °C

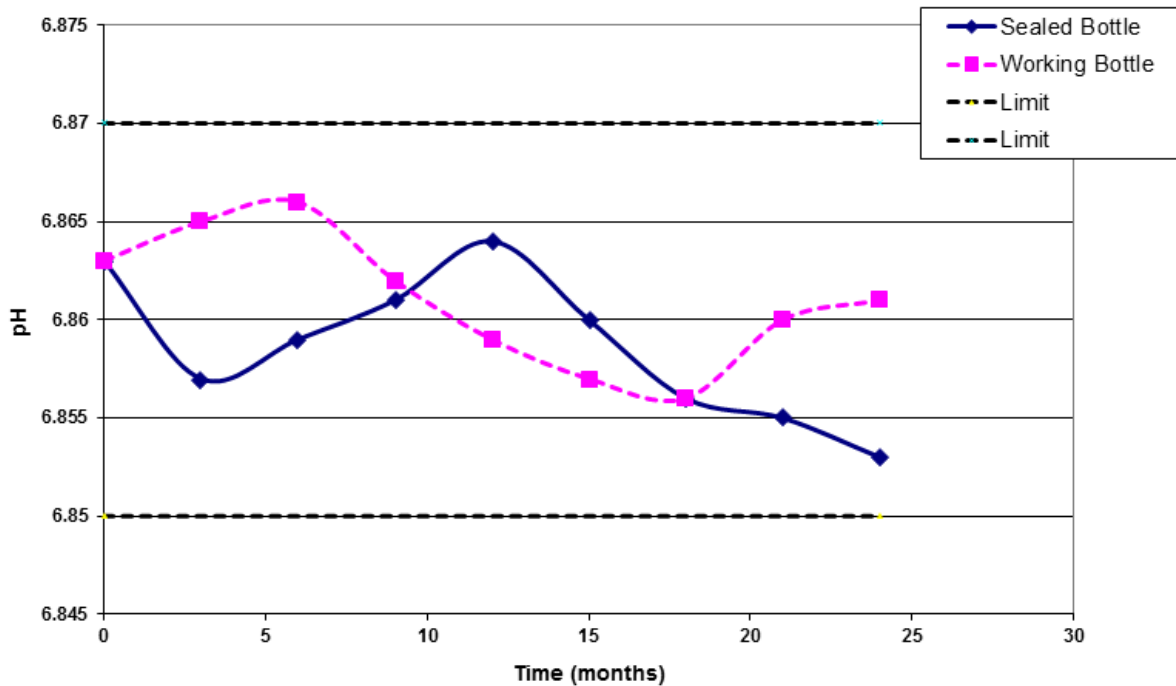
pH Measurement:

The test Method used for 1060525 was TPPHB. Measured with a combination glass electrode after multiple point calibration with reference materials. It is certified traceable to the following National Institute of Standards and Technology (USA), SRM 185h Potassium Hydrogen Phthalate, SRM 186-I-g Potassium Dihydrogen Phosphate and SRM 186-II-g Disodium Hydrogen Phosphate. The uncertainty of measurement has been calculated not to exceed $\pm 0.01\text{pH}$ at 95% confidence level, i.e. coverage factor $k = 2$.

Buffer Substance:

Potassium di-hydrogen Phosphate, Disodium Hydrogen Phosphate.

pH 6.86 Stability Study



Product No: 1068805CTT

Nominal Value: pH6.86 @25 °C

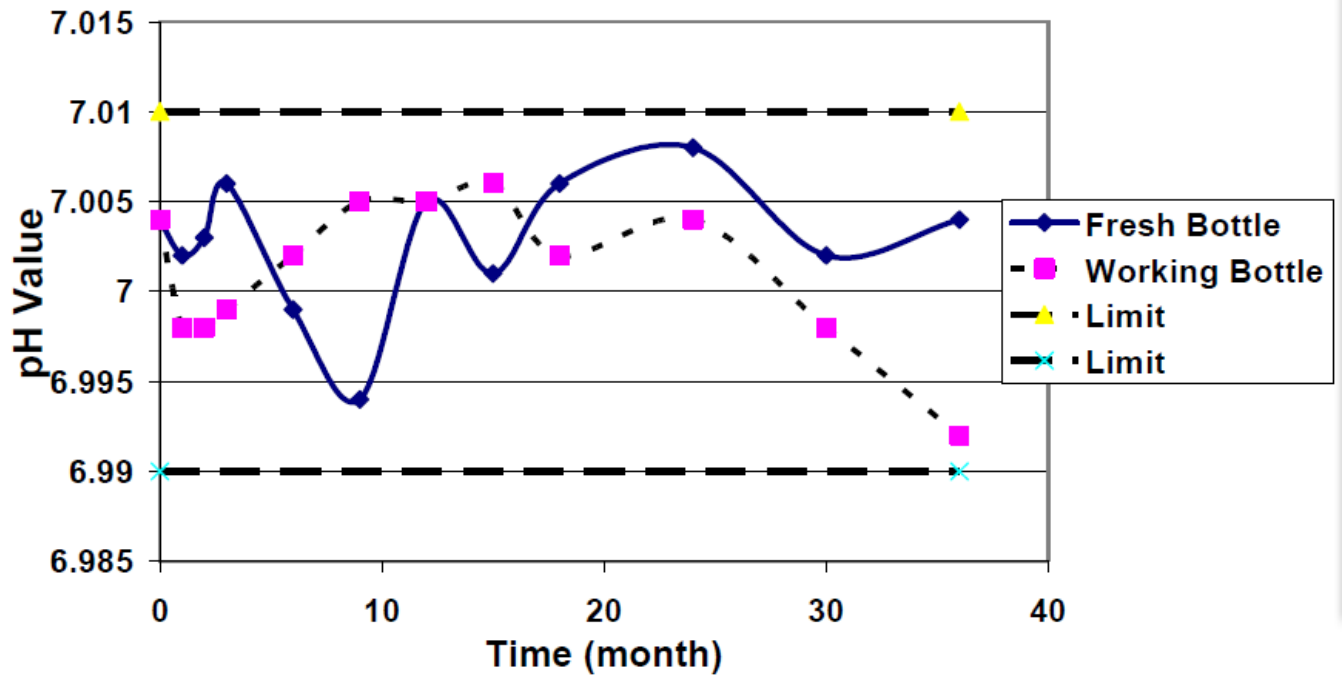
pH Measurement:

The test Method used for 1068805CTT was TPPHB. Measured with a combination glass electrode after multiple point calibration with reference materials. It is certified traceable to the following National Institute of Standards and Technology (USA), SRM 191d-I Sodium Bicarbonate, SRM 191d-II Sodium Carbonate, SRM 186-I-g Potassium Dihydrogen Phosphate and SRM 186-II-g Disodium Hydrogen Phosphate. The uncertainty of measurement has been calculated not to exceed $\pm 0.01\text{pH}$ at 95% confidence level, i.e. coverage factor $k = 2$.

Buffer Substance:

Potassium di-hydrogen Phosphate, Disodium Hydrogen Phosphate.

pH 7 Stability Study



Product No: 1070525 &1070525CTT

Nominal Value: pH7.00 @25 °C

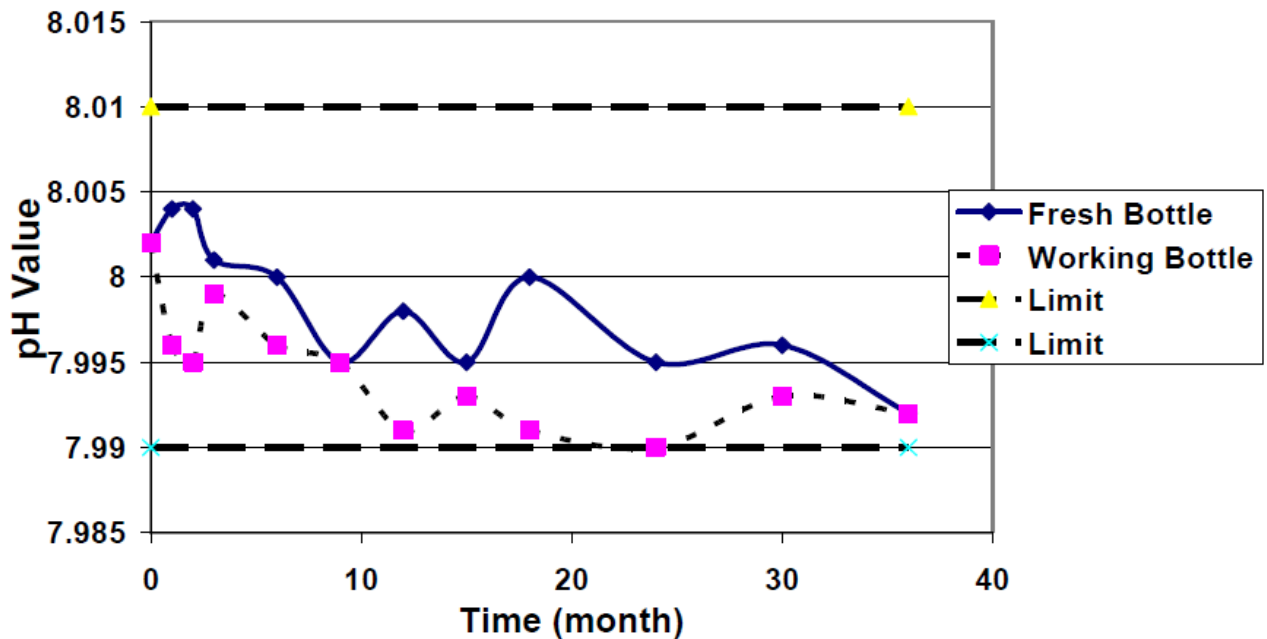
pH Measurement:

The test Method used for 1070525 was TPPHB. Measured with a combination glass electrode after multiple point calibration with reference materials. It is certified traceable to the following National Institute of Standards and Technology (USA), SRM 185h Potassium Hydrogen Phthalate, SRM 186-I-g Potassium Dihydrogen Phosphate and SRM 186-II-g Disodium Hydrogen Phosphate. The uncertainty of measurement has been calculated not to exceed $\pm 0.01\text{pH}$ at 95% confidence level, i.e. coverage factor $k = 2$.

Buffer Substance:

Potassium di-hydrogen Phosphate, Disodium Hydrogen Phosphate

pH 8 Stability Study



Product No: 1080525

Nominal Value: pH8.00 @25 °C

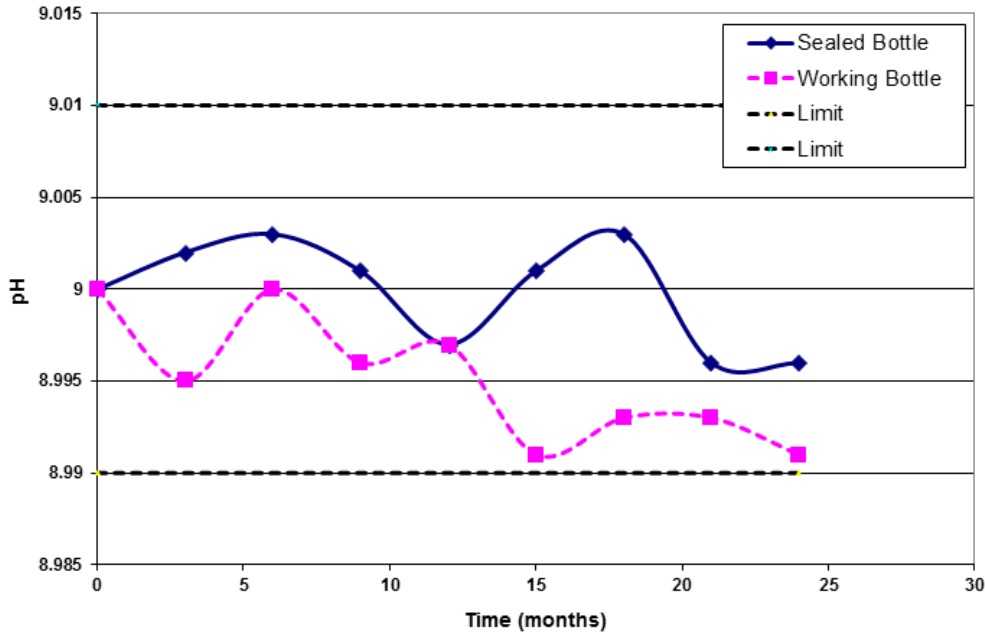
pH Measurement:

The test Method used for 1080525 was TPPHB. Measured with a combination glass electrode after multiple point calibration with reference materials. It is certified traceable to the following National Institute of Standards and Technology (USA), SRM 191d-I Sodium Bicarbonate, SRM 191d-II Sodium Carbonate, SRM 186-I-g Potassium Dihydrogen Phosphate and SRM 186-II-g Disodium Hydrogen Phosphate. The uncertainty of measurement has been calculated not to exceed $\pm 0.01\text{pH}$ at 95% confidence level, i.e. coverage factor $k = 2$.

Buffer Substance:

Di-sodium tetraborate decahydrate, 1M Hydrochloric Acid.

pH 9.00 Stability Study



Product No: 1090525 & 1090525CTT

Nominal Value: pH9.00 @25 °C

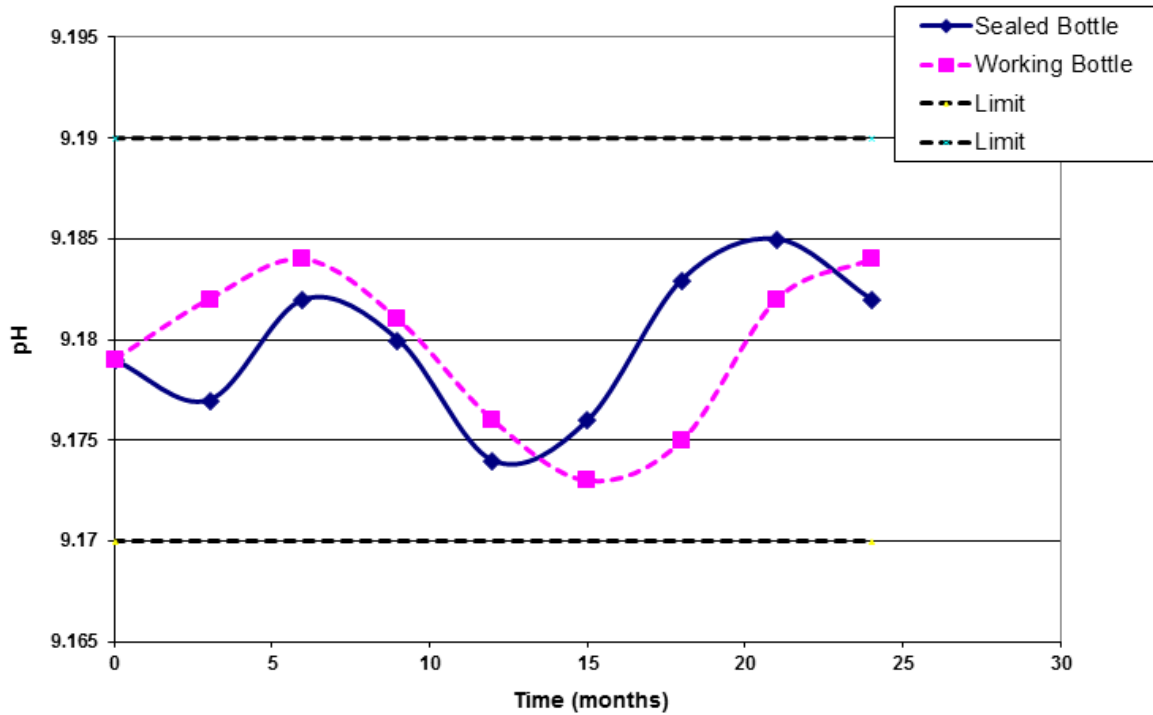
pH Measurement:

The test Method used for 1090525 was TPPHB. Measured with a combination glass electrode after multiple point calibration with reference materials. It is certified traceable to the following National Institute of Standards and Technology (USA), SRM 191d-I Sodium Bicarbonate, SRM 191d-II Sodium Carbonate, SRM 186-I-g Potassium Dihydrogen Phosphate and SRM 186-II-g Disodium Hydrogen Phosphate. The uncertainty of measurement has been calculated not to exceed $\pm 0.01\text{pH}$ at 95% confidence level, i.e. coverage factor $k = 2$.

Buffer Substance:

Di-sodium tetraborate decahydrate, 1M Hydrochloric Acid.

pH 9.18 Stability Study



Product No: 109180CTT

Nominal Value: pH9.18 @25 °C

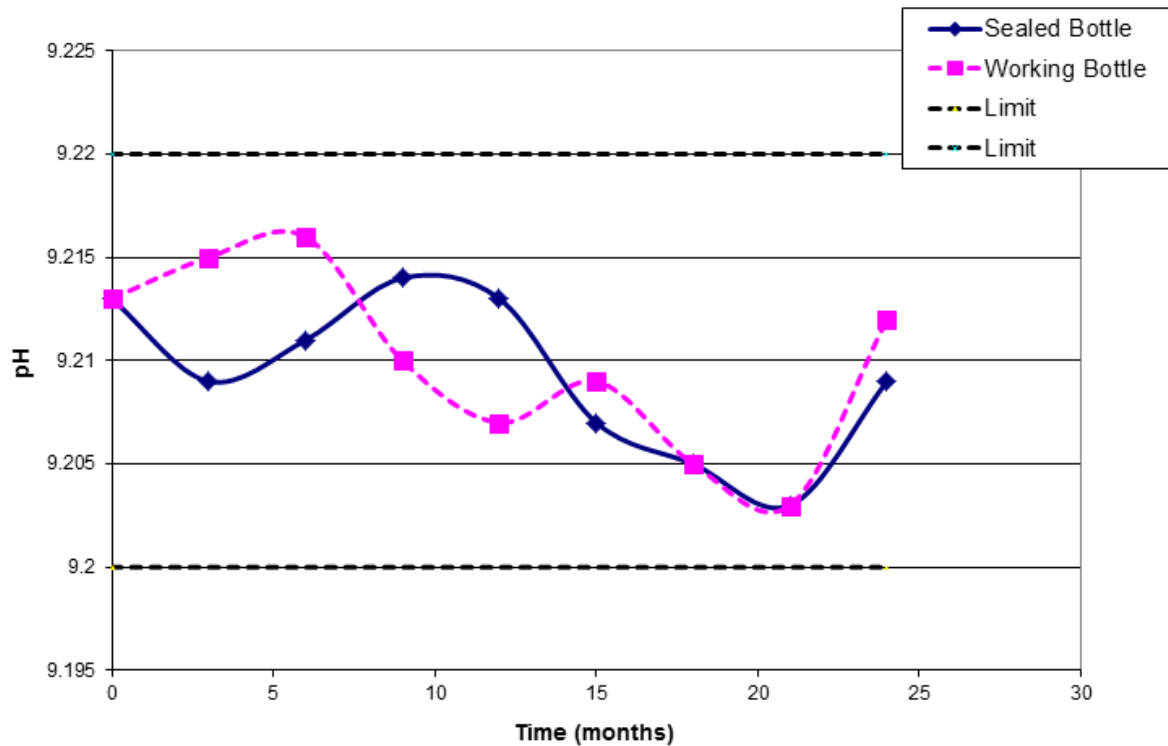
pH Measurement:

The test Method used for 109180CTT was TPPHB. Measured with a combination glass electrode after multiple point calibration with reference materials. It is certified traceable to the following National Institute of Standards and Technology (USA), SRM 191d-I Sodium Bicarbonate, SRM 191d-II Sodium Carbonate, SRM 186-I-g Potassium Dihydrogen Phosphate and SRM 186-II-g Disodium Hydrogen Phosphate. The uncertainty of measurement has been calculated not to exceed $\pm 0.01\text{pH}$ at 95% confidence level, i.e. coverage factor $k = 2$.

Buffer Substance:

Di-sodium tetraborate decahydrate

pH 9.21 Stability Study



Product No: 1092125CTT

Nominal Value: pH9.21 @25 °C

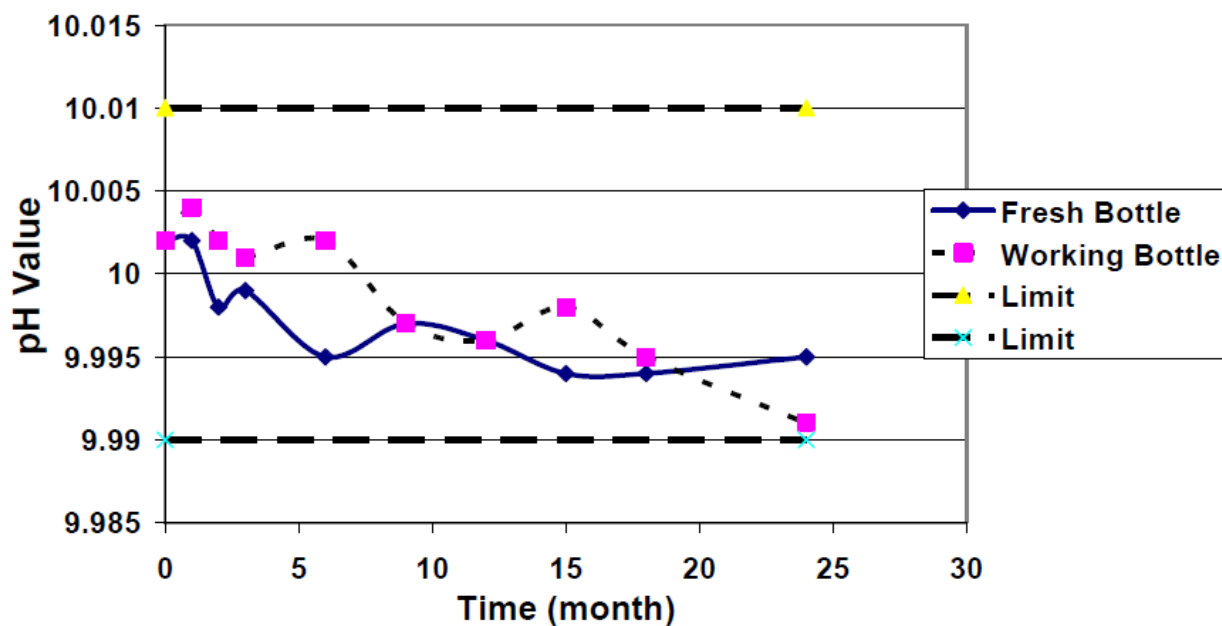
pH Measurement:

The test Method used for 1092125CTT was TPPHB. Measured with a combination glass electrode after multiple point calibration with reference materials. It is certified traceable to the following National Institute of Standards and Technology (USA), SRM 185i Potassium Hydrogen Phthalate, SRM 186-I-g Potassium Dihydrogen Phosphate and SRM 186-II-g Disodium Hydrogen Phosphate. The uncertainty of measurement has been calculated not to exceed $\pm 0.01\text{pH}$ at 95% confidence level, i.e. coverage factor $k = 2$.

Buffer Substance:

Di-sodium tetraborate decahydrate, 1M Hydrochloric Acid.

pH 10 Stability Study



Product No: 1100525

Nominal Value: pH10.00 @25 °C

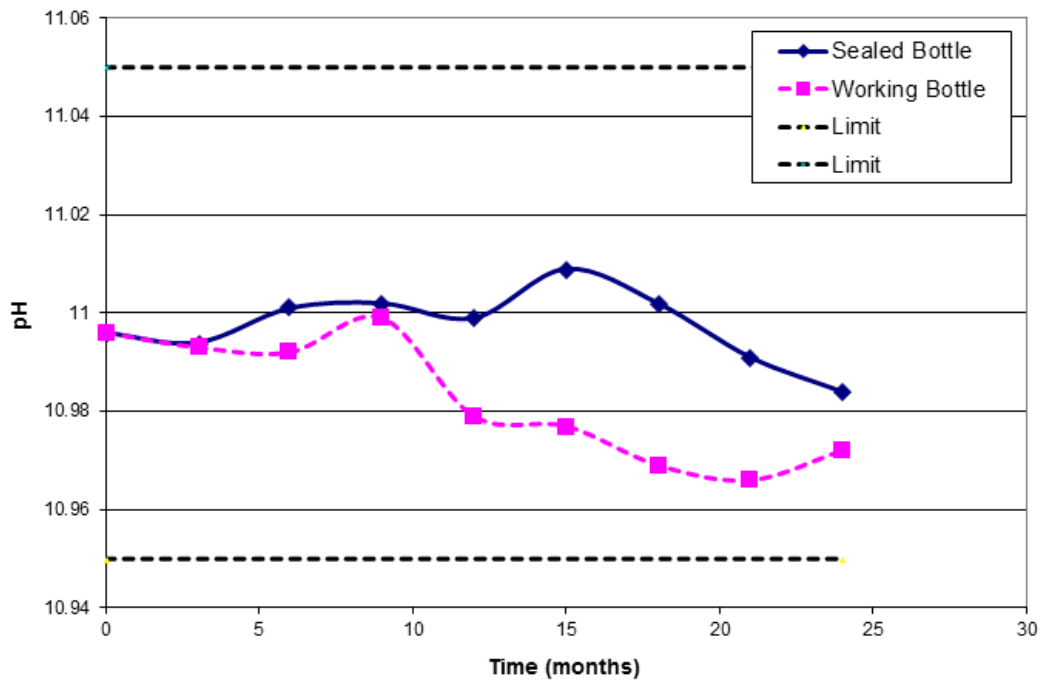
pH Measurement:

The test Method used for 1100525 was TPPHB. Measured with a combination glass electrode after multiple point calibration with reference materials. It is certified traceable to the following NIST(USA), SRM 191d-I Sodium Bicarbonate, SRM 191d-II Sodium Carbonate, SRM 186-I-g Potassium Dihydrogen Phosphate and SRM 186-II-g Disodium Hydrogen Phosphate. The uncertainty of measurement has been calculated not to exceed $\pm 0.01\text{pH}$ at 95% confidence level, i.e. coverage factor $k = 2$.

Buffer Substance:

Di-sodium Tetraborate, Sodium Hydroxide.

pH 11.00 Stability Study



Product No: 1110525

Nominal Value: pH11.00 @25 °C

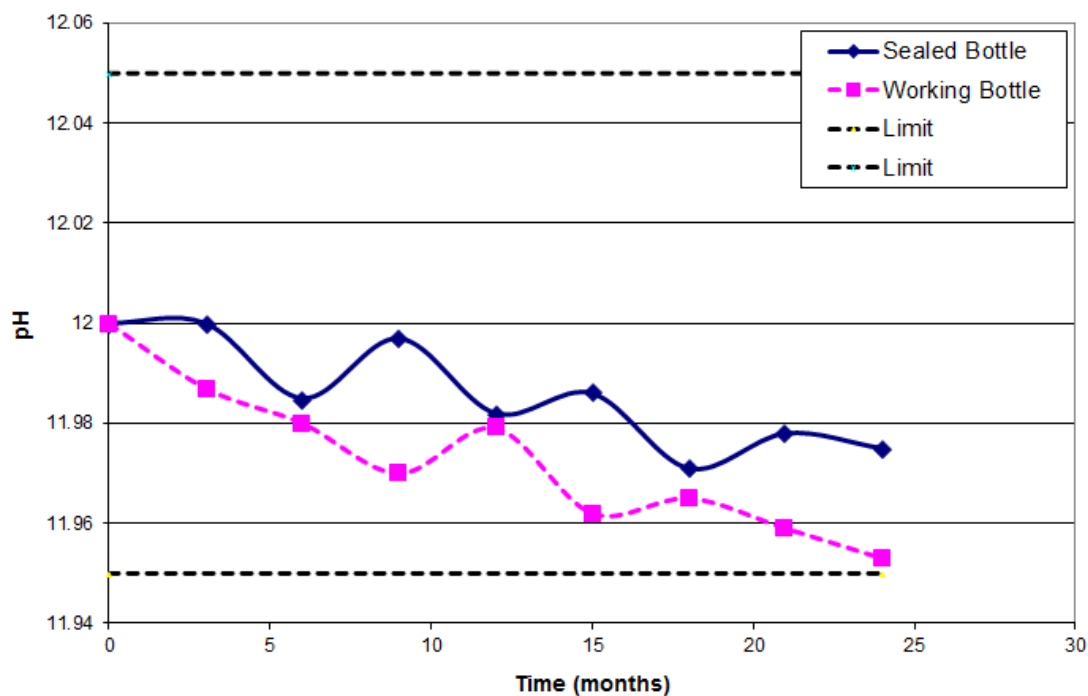
pH Measurement:

The test Method used for 1110525 was TPPHB. Measured with a combination glass electrode after multiple point calibration with reference materials. It is certified traceable to the following NIST(USA), SRM 191d-I Sodium Bicarbonate, SRM 191d-II Sodium Carbonate, SRM 186-I-g Potassium Dihydrogen Phosphate and SRM 186-II-g Disodium Hydrogen Phosphate. The uncertainty of measurement has been calculated not to exceed $\pm 0.05\text{pH}$ at 95% confidence level, i.e. coverage factor $k = 2$.

Buffer Substance:

Glycine, Sodium Chloride, Sodium Hydroxide.

pH 12.00 Stability Study



Product No: 1120525

Nominal Value: pH12.00 @25 °C

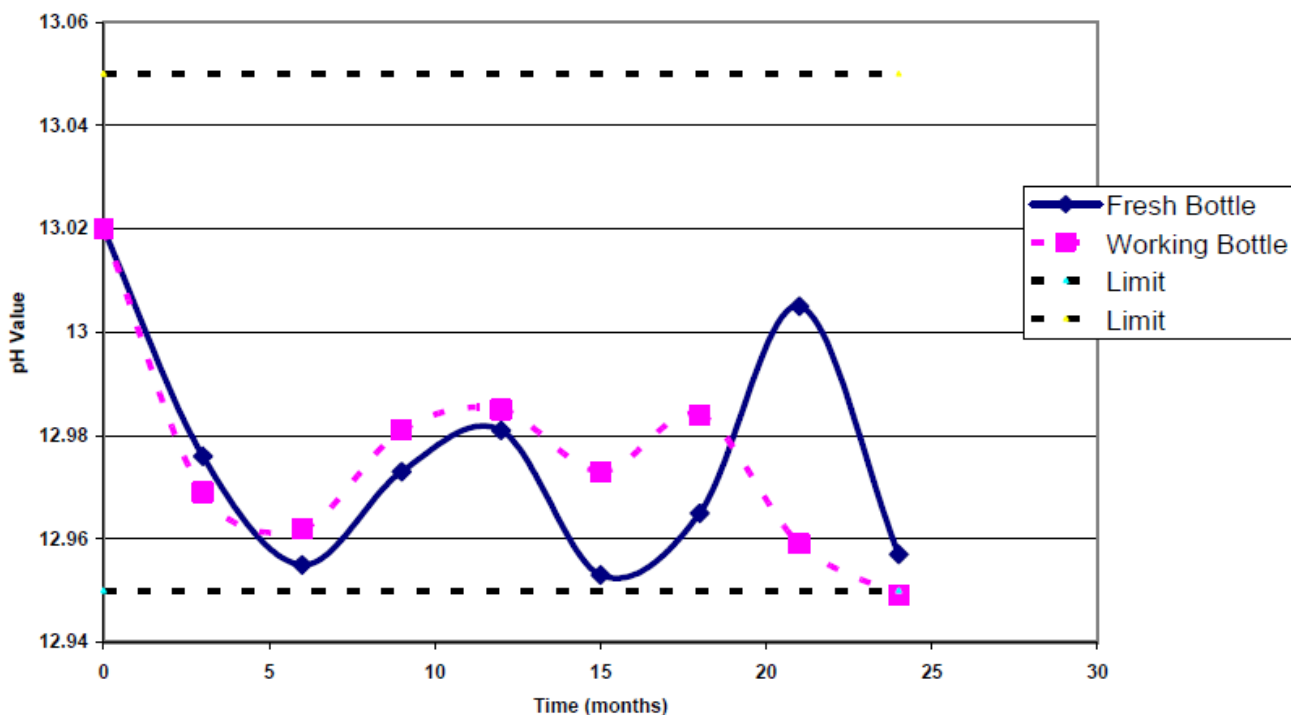
pH Measurement:

The test Method used for 1120525 was TPPHB. Measured with a combination glass electrode after multiple point calibration with reference materials. It is certified traceable to the following NIST(USA), SRM 191d-I Sodium Bicarbonate, SRM 191d-II Sodium Carbonate, SRM 186-I-g Potassium Dihydrogen Phosphate and SRM 186-II-g Disodium Hydrogen Phosphate. The uncertainty of measurement has been calculated not to exceed $\pm 0.05\text{pH}$ at 95% confidence level, i.e. coverage factor $k = 2$.

Buffer Substance:

Glycine, Sodium Chloride, Sodium Hydroxide.

pH 13 Stability Study



Product No: 1130525

Nominal Value: pH13.00 @25 °C

pH Measurement:

The test Method used for 1130525 was TPPHB. Measured with a combination glass electrode after multiple point calibration with reference materials. It is certified traceable to the following National Institute of Standards and Technology (USA), SRM 191d-I Sodium Bicarbonate, SRM 191d-II Sodium Carbonate, SRM 186-I-g Potassium Dihydrogen Phosphate and SRM 186-II-g Disodium Hydrogen Phosphate. The uncertainty of measurement has been calculated not to exceed $\pm 0.05\text{pH}$ at 95% confidence level, i.e. coverage factor $k=2$.

Buffer Substance:

Glycine, Sodium Hydroxide, Sodium Chloride.

Detailed Data:

Month	pH1.00A	pH1.00B	pH2.00A	pH2.00B	pH3.00A	pH3.00B
0	1.003	1.003	1.997	1.997	3.001	3.001
3	0.999	1.007	2.003	2.003	3.001	3.002
6	0.993	1.011	2.002	1.982	2.998	3.014
9	0.991	1.008	1.996	1.989	2.998	3.005
12	0.999	1.006	2.009	2.005	2.999	3.008
15	1.004	1.012	1.994	2.001	3.009	2.998
18	1.001	1.009	1.997	2.002	3.000	3.001
21	0.999	0.995	2.016	2.003	3.004	2.996
24	0.998	1.003	1.998	2.005	3.008	2.994

Month	pH4.00A	pH4.00B	pH4.01A	pH4.01B	pH5.00A	pH5.00B
0	4.001	4.001	4.012	4.012	4.999	4.999
3	4.006	4.005	4.015	4.004	4.999	5.003
6	4.003	4.008	4.007	4.014	4.999	5.001
9	4.000	4.003	4.017	4.016	4.997	5.001
12	4.002	4.003	4.005	4.013	4.998	4.996
15	4.004	4.006	4.015	4.005	4.998	4.998
18	4.005	4.007	4.011	4.014	5.001	5.000
21	4.007	4.003	4.003	4.015	4.995	4.998
24	4.000	4.008	4.015	4.011	5.002	5.004

Month	pH6.00A	pH6.00B	pH6.86A	pH6.86B	pH7.00A	pH7.00B
0	6.001	6.001	6.863	6.863	7.005	7.005
3	5.997	6.000	6.857	6.865	7.000	7.002
6	6.000	6.002	6.859	6.866	6.999	7.000
9	5.999	5.995	6.861	6.862	6.997	7.006
12	5.997	6.000	6.864	6.859	7.001	7.002
15	5.998	5.992	6.860	6.857	6.999	7.002
18	5.998	5.998	6.856	6.856	6.997	7.000
21	5.994	5.993	6.855	6.860	6.991	6.997
24	5.994	5.993	6.853	6.861	6.995	6.996

Month	pH8.00A	pH8.00B	pH9.00A	pH9.00B	pH9.18A	pH9.18B
0	8.001	8.001	9.000	9.000	9.179	9.179
3	7.991	8.003	9.002	8.995	9.177	9.182
6	7.995	8.003	9.003	9.000	9.182	9.184
9	7.993	8.005	9.001	8.996	9.180	9.181
12	7.995	8.007	8.997	8.997	9.174	9.176
15	7.994	7.996	9.001	8.991	9.176	9.173
18	7.999	7.990	9.003	8.993	9.183	9.175
21	7.991	7.995	8.996	8.993	9.185	9.182
24	7.995	7.998	8.996	8.991	9.182	9.184

Month	pH9.21A	pH9.21B	pH10.00A	pH10.00B	pH11.00A	pH11.00B
0	9.213	9.213	10.000	10.000	10.996	10.996
3	9.209	9.215	10.001	9.997	10.994	10.993
6	9.211	9.216	10.003	10.000	11.001	10.992
9	9.214	9.210	9.999	9.991	11.002	10.999
12	9.213	9.207	9.992	9.994	10.999	10.979
15	9.207	9.209	10.003	9.992	11.009	10.977
18	9.205	9.205	10.001	9.995	11.002	10.969
21	9.203	9.203	10.001	9.993	10.991	10.966
24	9.209	9.212	9.993	9.991	10.984	10.972

Month	pH12.00A	pH12.00B	pH13.00A	pH13.00B
0	12.000	12.000	13.020	13.020
3	12.000	11.987	12.976	12.969
6	11.985	11.980	12.955	12.962
9	11.997	11.970	12.973	12.981
12	11.982	11.979	12.981	12.985
15	11.986	11.962	12.953	12.973
18	11.971	11.965	12.965	12.984
21	11.978	11.959	13.005	12.959
24	11.975	11.953	12.957	12.949

Note: A stands for Sealed or Fresh bottle, B stands for working bottle

Conclusion:

The pH buffers' stability studies were performed on both freshly opened bottles at each testing time and a 'working bottle' from which successive test aliquots were removed for analysis at each testing time. Both types of bottle were stored within our warehouse for the duration of the stability study (temperature range approx 10°C to 25°C). For both types of sample, the pH value remained within the product specification for the entire product shelf- life. This validates the claim that the expiry date of Reagecon's pH buffers does not need to be reduced to a short period following the initial opening of the bottle. As a result of these stability studies you do not have to throw away your Reagecon pH buffer after 3 months of opening.