Diagnostics Biochem Canada Inc.
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Dehydroepiandrosterone (DHEA) ELISA

REF CAN-DH-490	CE IVD
Effective Date: October 17, 2023	Version: CE-9.1

1. INTENDED PURPOSE & USE

For the quantitative measurement of Dehydroepiandrosterone (DHEA) in human serum by an ELISA (Enzyme-Linked Immunosorbent Assay).

This kit is intended for professional use only and is for laboratory use only. For *in vitro* diagnostic use only. Intended to be used manually but may be adaptable to open automated analyzers. The user is responsible for validating the performance of this kit with any automated analyzers.

2. LIMITATIONS RELATED TO INTENDED PURPOSE & USE

1. This test is not intended to be used for screening purposes.
2. This test is not intended for home testing or self-testing.
3. The kit is calibrated for the determination of DHEA in human serum. The kit is not calibrated for the determination of DHEA in other specimens of human or animal origin.
4. The results obtained with this kit shall never be used as the sole basis for a clinical diagnosis and for therapeutic decisions.
5. Although common interfering substances have been evaluated with this test, other substances that have not been evaluated such as drugs and the occurrence of heterophilic antibodies in individuals regularly exposed to animals or animal products have the potential of causing interferences

3. SUPPLEMENTAL INFORMATION

Dehydroepiandrosterone (DHEA) is a C19 steroid produced in the adrenal cortex and to a lesser extent in the gonads. DHEA serves as a precursor in testosterone and estrogen synthesis. Due to the presence of a 17-oxo-group, DHEA has relatively weak androgenic activity, which has been estimated at ~10% that of testosterone. However, in neonates, peripubertal children and in adult women, circulating DHEA levels may be several-fold higher than testosterone concentrations, and rapid peripheral tissue conversion to more potent androgens (androstenedione and testosterone) and estrogens may occur. Moreover, DHEA has a relatively low affinity for sex hormone-binding globulin—a factor that may enhance the physiological biopotency of DHEA.
The physiological functions of DHEA are still the subject of investigation. DHEA reportedly plays a role in immune function, lipid metabolism, cholesterol, the nervous system, ageing and protection against viral infection. Serum DHEA levels are relatively high in the fetus and neonates, low during childhood, and increase during puberty until the third decade of life. No consistent change in serum DHEA levels occurs during the menstrual cycle or pregnancy. DHEA has a rapid metabolic clearance rate as compared to its sulfated conjugate. Because of this, serum DHEA levels are 100–1000 fold lower than DHEA-Sulfate levels. In addition, serum DHEA levels show significant diurnal variation which is dependent on adrenocorticotropic hormone (ACTH). Measurement of serum DHEA is a useful marker of adrenal androgen synthesis. Abnormally low levels may occur in hypoadrenalism, and elevated levels may occur in several conditions, such as 21-hydroxylase and 3b-hydroxysteroid dehydrogenase deficiencies and some cases of female hirsutism.

4. PRINCIPLE OF THE TEST

The DHEA ELISA is a competitive immunoassay. Competition occurs between DHEA present in calibrators, controls, specimen samples and an enzyme-labelled antigen (HRP conjugate) for a limited number of anti-DHEA antibody binding sites on the microplate wells. After a washing step that removes unbound materials, the TMB substrate (enzyme substrate) is added which reacts with HRP to form a blue-coloured product that is inversely proportional to the amount of DHEA present. Following an incubation, the enzymatic reaction is terminated by the addition of the stopping solution, converting the blue colour to a yellow colour. The absorbance is measured on a microplate reader at 450 nm. A set of calibrators is used to plot a calibrator curve from which the amount of DHEA in specimen samples and controls can be directly read.

5. PROCEDURAL CAUTIONS AND WARNINGS

1. This kit is for use by trained laboratory personnel (professional use only). For laboratory *in vitro* use only.
2. Practice good laboratory practices when handling kit reagents and specimens. This includes:
   - Do not pipette by mouth.
   - Do not smoke, drink, or eat in areas where specimens or kit reagents are handled.
   - Wear protective clothing and disposable gloves.
   - Wash hands thoroughly after performing the test.
   - Avoid contact with eyes; use safety glasses; in case of contact with eyes, flush eyes with water immediately and contact a doctor.
3. Users should have a thorough understanding of this protocol for the successful use of this kit. Reliable performance will only be attained by strict and careful adherence to the instructions provided.
4. Do not use the kit beyond the expiry date stated on the label.
5. If the kit reagents are visibly damaged, do not use the test kit.
6. Do not use kit components from different kit lots within a test and do not use any component beyond the expiration date printed on the label.
7. All kit reagents and specimens must be brought to room temperature and mixed gently but thoroughly before use. Avoid repeated freezing and thawing of specimens.
8. When the use of water is specified for dilution or reconstitution, use deionized or distilled water.
9. Immediately after use, each individual component of the kit must be returned to the recommended storage temperature stated on the label.
10. A calibrator curve must be established for every run.
11. It is recommended to all customers to prepare their own control materials or serum pools which should be included in every run at a high and low level for assessing the reliability of results.
12. The controls (included in kit) must be included in every run and their results must fall within the ranges stated in the quality control certificate; a failed control result might indicate improper procedural techniques or pipetting, incomplete washing, or improper reagent storage.
13. When dispensing the substrate and stopping solutions, do not use pipettes in which these liquids will come into contact with any metal parts.
14. The TMB Substrate is sensitive to light and should remain colourless if properly stored. Instability or contamination may be indicated by the development of a blue colour, in which case it should not be used.
15. Do not use grossly hemolyzed, grossly lipemic, icteric or improperly stored serum.
16. Samples or controls containing azide or thimerosal are not compatible with this kit, they may lead to false results.
17. Samples values above the measuring range of the kit may be reported as >40 ng/mL. If further dilution and retesting is required, only the DHEA sample diluent may be used to dilute serum samples. The use of any other reagent may lead to false results.
18. Avoid microbial contamination of reagents.
19. To prevent the contamination of reagents, use a new disposable pipette tip for dispensing each reagent, sample, calibrator, and control.
20. To prevent the contamination of reagents, do not pour reagents back into the original containers.
21. Kit reagents must be regarded as hazardous waste and disposed of according to local and/or national regulations.
22. Consumables used with the kit that are potentially biohazardous (e.g., pipette tips, bottles or containers containing human materials) must be handled according to biosafety practices to minimize the risk of infection and disposed of according to local and/or national regulations relating to biohazardous waste.
23. This kit contains 1 M sulfuric acid in the stopping solution component. Do not combine acid with waste material containing sodium azide or sodium hypochlorite.
24. The use of safety glasses, and disposable plastic, is strongly recommended when manipulating biohazardous or bio-contaminated solutions.
25. Proper calibration of the equipment used with the test, such as the pipettes and absorbance microplate reader, is required.
26. If a microplate shaker is required for the assay procedure, the type and speed of shaker required is stated in the REAGENTS AND EQUIPMENT NEEDED BUT NOT PROVIDED section. Both the type and speed of shaker used can influence the optical densities and test results. If a different type of shaker and/or speed is used, the user is responsible for validating the performance of the kit.
27. Do not reuse the microplate wells, they are for SINGLE USE only.
28. To avoid condensation within the microplate wells in humid environments, do not open the pouch containing the microplate until it has reached room temperature.
29. Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

6. SAFETY CAUTIONS AND WARNINGS

6.1 BIOHAZARDS

The reagents should be considered a potential biohazard and handled with the same precautions applied to blood specimens. All human specimens should be considered a potential biohazard and handled as if capable of transmitting infections and in accordance with good laboratory practices.

The DHEA sample diluent (not provided with the kit), contains processed human serum/plasma that has been tested by approved methods and found to be negative for the presence of HBsAg and antibodies to HCV, HIV 1/2 and HIV NAT. However, no test method can offer complete assurance that any viable pathogens are absent. Therefore, these components should be considered a potential biohazard and handled with the same precautions as applied to any blood specimen, following good laboratory practices.

6.2 CHEMICAL HAZARDS

Avoid direct contact with any of the kit reagents. Specifically avoid contact with the TMB Substrate (contains tetramethylbenzidine) and Stopping Solution (contains sulfuric acid). If contacted with any of these reagents, wash with plenty of water and refer to SDS for additional information.

7. SPECIMEN COLLECTION, STORAGE AND PRE-TREATMENT

7.1 Specimen Collection & Storage

Approximately 0.1 mL of serum is required per duplicate determination. Collect 4–5 mL of venous blood into an appropriately labelled tube and allow it to clot. Centrifuge at room temperature and carefully transfer the serum into a new storage tube or container. Serum samples may be stored at 2-8°C for up to 24 hours or at -10°C or lower for up to 7 days. Specimens may be more stable than indicated.
Consider all human specimens as possible biohazardous materials and take appropriate precautions when handling.

7.2 Specimen Pre-Treatment

Specimen pre-treatment is not required.

8. REAGENTS AND EQUIPMENT NEEDED BUT NOT PROVIDED

1. Calibrated single-channel pipette to dispense 25 µL.
2. Calibrated multi-channel pipettes to dispense 50 µL, 100 µL and 150 µL.
3. Calibrated multi-channel pipettes to dispense 350 µL (if washing manually).
4. Automatic microplate washer (recommended).
5. Disposable pipette tips.
6. Distilled or deionized water.
7. Calibrated absorbance microplate reader with a 450 nm filter and an upper OD limit of 3.0 or greater.
8. DHEA Sample Diluent. Only required if it is necessary to dilute samples >40 ng/mL. Must be ordered separately (REF#: CAN-DH-490-11).

9. REAGENTS PROVIDED

1. MPL — Microplate

Contents:	One anti-DHEA polyclonal antibody-coated 96-well (12x8) microplate in a resealable pouch with desiccant.
Format:	Ready to Use
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

2. HRP CONJ — HRP Conjugate

Contents:	One bottle containing DHEA-Horse Radish Peroxidase (HRP) conjugate in a protein-based buffer with a non-mercury preservative.
Format:	Ready to Use
Volume:	14 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

3. CAL A – F — Calibrator A – F

Contents:	Six bottles of calibrator containing specified DHEA concentrations. Protein-based buffer with a non-mercury preservative. Prepared by spiking buffer with defined quantities of DHEA. Listed below are approximate concentrations, please refer to vial labels for exact concentrations. Concentrations: 0, 0.2, 1, 5, 15, 40 ng/mL.
Format:	Ready to Use
Volume:	Calibrator A-F: 1.0 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

4. CONTROL 1 – 2 — Control 1 – 2

Contents:	Two bottles of control containing different DHEA concentrations. Protein-based buffer with a non-mercury preservative. Prepared by spiking buffer with defined quantities of DHEA. Refer to the QC certificate for the target values and acceptable ranges.
Format:	Ready to Use
Volume:	1.0 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

5. TMB | SUB — TMB Substrate

Contents:	One bottle containing tetramethylbenzidine and hydrogen peroxide in a non-DMF or DMSO containing buffer.
Format:	Ready to Use
Volume:	16 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

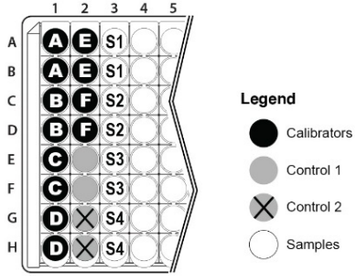
6. STOP — Stopping Solution

Contents:	One bottle containing 1M sulfuric acid.
Format:	Ready to Use
Volume:	6 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.
Safety:	Refer to product SDS.  **Warning**

7. WASH | BUFF | CONC — Wash Buffer Concentrate

Contents:	One bottle containing buffer with a non-ionic detergent and a non-mercury preservative.
Format:	Concentrated; Requires Preparation
Volume:	50 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks. Following Preparation: The wash buffer working solution is stable for 2 weeks following preparation, assuming Good Laboratory Practices are adhered to. To prevent microbial growth, prepare the wash buffer working solution in a clean container and store under refrigerated conditions (2-8°C) when not in use.
Preparation of Wash Buffer Working Solution:	**X10 Dilute 1:10 Before Use** Dilute 1:10 in distilled or deionized water before use. If the whole microplate is to be used dilute 50 mL of the wash buffer concentrate in 450 mL of distilled or deionized water.

10. RECOMMENDED ASSAY LAYOUT



11. ASSAY PROCEDURE

Specimen Pre-Treatment: None

All kit components, controls and specimen samples must reach room temperature prior to use. Calibrators, controls, and specimen samples should be assayed in duplicate. Once the procedure has been started, all steps should be completed without interruption.

1. After all kit components have reached room temperature, **mix** gently by inversion.
2. **Prepare** the Wash Buffer Working Solution (See section *9. Reagents Provided* section, *7. Wash Buffer Concentrate*).
3. **Plan** the microplate wells to be used for calibrators, controls, and samples. See section *10. Recommended Assay Layout.* Remove the strips from the microplate frame that will not be used and place them in the bag with desiccant. Reseal the bag with the unused strips and return it to the refrigerator.
4. **Pipette 25 µL** of each calibrator, control, and specimen sample into assigned wells.
5. **Pipette 100 µL** of the HRP Conjugate into each well (the use of a multi-channel pipette is recommended).
6. Gently tap the microplate frame for 10 seconds to mix the contents of the wells and **incubate** the microplate at room temperature (no shaking) for **90 minutes.**
7. **Wash** the microplate wells with an automatic microplate washer (preferred) or manually as stated below.

   Automatic: Using an automatic microplate washer, perform a **3-cycle** wash using **350 µL/well** of Wash Buffer Working Solution (3 x 350 µL). One cycle consists of aspirating all wells then filling each well with 350 µL of Wash Buffer Working Solution. After the final wash cycle, aspirate all wells and then tap the microplate firmly against absorbent paper to remove any residual liquid.

   Manually: For manual washing, perform a **3-cycle** wash using **350 µL/well** of Wash Buffer Working Solution (3 x 350 µL). One cycle consists of aspirating all wells by briskly emptying the contents of the wells over a waste container, then pipetting 350 µL of Wash Buffer Working Solution into each well using a multi-channel pipette. After the final wash cycle, aspirate all wells by briskly emptying the contents over a waste container and then tap the microplate firmly against absorbent paper to remove any residual liquid.
8. **Pipette 150 µL** of TMB Substrate into each well (the use of a multi-channel pipette is recommended).
9. Gently tap the microplate frame for 10 seconds to mix the contents of the wells and **incubate** the microplate at room temperature (no shaking) for **15-20 minutes**.
10. **Pipette 50 µL** of Stopping Solution into each well (the use of a multi-channel pipette is recommended) in the same order and speed as was used for addition of the TMB Substrate. Gently tap the microplate frame to mix the contents of the wells.
11. **Measure** the optical density (absorbance) in the microplate wells using an absorbance microplate reader set to 450 nm, within 20 minutes after addition of the Stopping Solution.

12. CALCULATIONS

1. Calculate the mean optical density for each calibrator, control and specimen sample duplicate.
2. Use a 4-parameter or 5-parameter curve fit with immunoassay software to generate a calibrator curve.
3. The immunoassay software will calculate the concentrations of the controls and specimen samples using the mean optical density values and the calibrator curve.
4. If a sample reads more than 40 ng/mL and needs to be diluted and retested, then dilute with DHEA Sample Diluent (see *Reagents And Equipment Needed But Not Provided* section) not more than 1:10. The result obtained must be multiplied by the dilution factor.

13. QUALITY CONTROL

When assessing the validity of the test results, the following criteria should be evaluated:

1. The calibrator A mean optical density meets the acceptable range as stated in the QC Certificate.
2. The calibrator with the highest concentration meets the % binding acceptable range as stated in the QC Certificate. % Binding = (OD of calibrator/OD of calibrator A) x 100.
3. The values obtained for the kit controls are within the acceptable ranges as stated in the QC certificate.
4. The results of any external controls that were used meet the acceptable ranges.

14. TYPICAL DATA

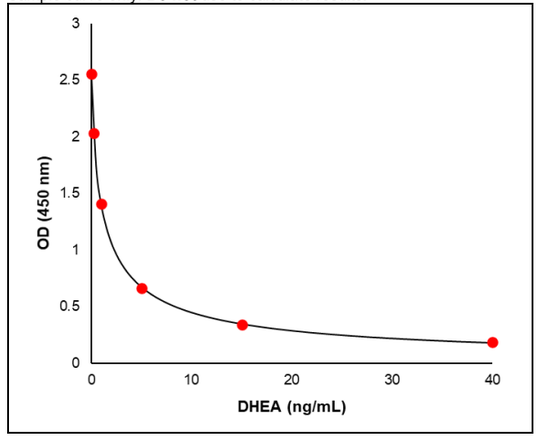
14.1 TYPICAL TABULATED DATA

Sample data only. **Do not** use to calculate results.

Calibrator	Mean OD (450 nm)	% Binding	Value (ng/mL)
A	2.555	100	0
B	2.033	80	0.2
C	1.411	55	1
D	0.663	26	5
E	0.345	14	15
F	0.190	7	40
Unknown	1.025	40	2.14

14.2 TYPICAL CALIBRATOR CURVE

Sample curve only. **Do not** use to calculate results.



15. PERFORMANCE CHARACTERISTICS

15.1 SENSITIVITY

The analytical sensitivity study was performed according to the CLSI EP17-A2 guideline. The Limit of Background (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) are summarized in the table below:

Parameter	DHEA (ng/mL)
LoB	0.048
LoD	0.092
LoQ	0.13

15.2 SPECIFICITY (CROSS-REACTIVITY)

The following compounds were tested for cross-reactivity with DHEA cross-reacting at 100%. ND=Not detectable.

Compound	% Cross-Reactivity
DHEA	100
11-Deoxycortisol	0.17
17-Hydroxypregnenolone	2.09
17α-Hydroxyprogesterone	0.19
Aldosterone	0.11
Androstenedione	0.40
Androsterone	0.14
Cholesterol	ND
Cortisol	0.07
Corticosterone	0.12
DHEAS	<0.02
DHT	0.37
Epiandrosterone	2.49
Estradiol	0.49
Estrone	0.22
Pregnenolone	9.48
Progesterone	0.23
Testosterone	0.31

15.3 INTERFERENCES

An interference study was performed according to the CLSI EP07 guideline. No significant interference was observed for concentrations of up to 5 g/L haemoglobin, 40 mg/dL unconjugated bilirubin, 30 mg/dL conjugated bilirubin, 15 mg/mL triglycerides, 2.4 µg/mL HAMAS, 2.4 µg/mL Biotin and 1688 IU/mL Rheumatoid Factor.

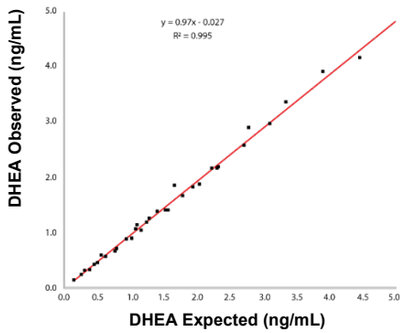
15.4 PRECISION

The precision study was performed according to the CLSI EP5-A3 guideline. The experimental protocol used a nested components-of-variance design with 8 serum samples, 10 testing days, two lots and two operators per day. Each operator ran two tests with two lots per day and two replicate measurements per run (a 10 x 2 x 2 x 2 design) using human serum samples. The results were analyzed with a two-way nested ANOVA and summarized in the table below.

Sample	Mean (ng/mL)	Within Run SD	Within Run CV%	Between Run SD	Between Run CV%	Total SD	Total CV%
1	1.20	0.05	3.8	0.12	10.2	0.13	10.9
2	3.50	0.09	2.7	0.29	8.3	0.31	8.7
3	8.88	0.25	2.8	0.54	6.1	0.64	7.2
4	3.26	0.10	3.0	0.27	8.4	0.29	9.0
5	2.81	0.10	3.5	0.25	8.7	0.26	9.4
6	1.38	0.04	3.2	0.14	10.1	0.16	11.5
7	13.28	0.36	2.7	0.95	7.1	1.08	8.1
8	20.20	0.51	2.5	1.65	8.2	1.73	8.6

15.5 LINEARITY

The linearity study was performed with four human serum samples covering the range of the assay and following the CLSI EP06-A guideline. The samples were diluted in the DHEA Sample Diluent at several equidistant concentration levels and up to ten percent (1:10), tested in quadruplicate, and the results compared to the predicted concentration. The statistical analysis shows that the assay is sufficiently linear up to a 1:10 dilution when using the DHEA sample diluent as the diluent.



15.6 RECOVERY

Low-value samples and high-value samples were mixed at different ratios and measured with the DHEA ELISA kit. The recovery (%) for each sample was calculated from the ratio between the results and the expected values. The recovery results from twelve samples were between 90 and 110%.

15.7 COMPARATIVE STUDIES

The DBC DHEA ELISA kit (y) was compared against a Liquid Chromatography-Mass Spectrometry (LC-MS/MS) method (x). The comparison of 98 serum samples yielded the following Passing-Bablok regression:
y = 0.65x + 0.61, r = 0.923

16. REFERENCE RANGES

Reference ranges were established using serum samples from 264 female donors between 18-63 years old and 130 male donors between 18-65 years old. The reference ranges were determined using a non-parametric method and are summarized in the table below.
Each laboratory shall establish their own reference ranges.

Adults	Age (years)	N	Median (ng/mL)	Mean (ng/mL)	95% Reference Range (ng/mL)
Males	18–65	130	2.80	3.04	1.33–6.48
Females	18–63	264	2.35	2.61	1.00–5.86

Children	Age (years)	N	Total Range* (ng/mL)
Males	1–9	28	0.20–1.5
	10–14	23	0.58–3.7
	15–18	14	1.50–3.6
Females	2–9	27	0.36–3.6
	10–14	21	0.47–5.5
	15–18	19	0.41–5.7

*Since the number of pediatric samples is insufficient to establish a 95% reference range, the total range is provided which shows the lowest to the highest value obtained in each age group.

17. LITERATURE

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18. SYMBOLS GLOSSARY

Symbol	Definition	Symbol	Definition
REF	Catalogue number		Manufacturer
LOT	Batch code		Biological risks
IVD	In vitro diagnostic medical device		Consult instructions for use
UDI	Unique Device Identifier	Rx ONLY	Prescription only: Device restricted to use by or on the order of a physician
X #	Dilute 1:# Before Use		Keep away from sunlight
QTY	Quantity	EC REP	Authorized representative in the European Community/ European Union
	Use-by date		Temperature limit
	Do not re-use	Σ	Contains sufficient for <n> tests
	Caution	RUO	For Research Use Only. Not for use in diagnostic procedures.

The definitions of symbols used for kit component names are described in the *Reagents Provided* section.

19. CHANGE HISTORY

Previous Version:	CE-9.0	**New Version:**	CE-9.1
Changes:	**20. GENERAL INFORMATION** **Change:** EC REP changed from Emergo Europe to MedEnvoy Global B.V.		

20. GENERAL INFORMATION

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EC REP **MedEnvoy Global B.V.**
Prinses Margrietplantsoen 33, Suite 123
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The Netherlands

Product Complaints

In the case of product complaints, the user shall submit in writing to the distributor or manufacturer a description of the complaint and provide accompanying data and/or information.

Warranty

DBC guarantees that the product is free of defects and will perform within the product specifications when the product is used prior to the expiration date, according to the intended purpose and use, and according to the instructions for use provided with the product. Any deviations from the intended purpose and use, instructions for use, modifications to kit components or use beyond the expiration date will invalidate any warranty claims.

Limitation of Liability

DBC liability in all circumstances whether in tort (including negligence) or at common law, and for any damage or loss, including but not limited to loss of profit and loss of sales, suffered whether direct, indirect, consequential, incidental or special is limited to the purchase price of the product(s) in question.